stryker

Hoffmann II

EN

INSTRUCTIONS FOR USE

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THIS DOCUMENT IS APPLICABLE TO USA AND CANADA

CONTENTS

Hoffmann II

ALL OF THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE

CAUTION

Federal law in the USA restricts this device to sale by or on the order of a physician. See product label for information regarding the specific product referenced in this package insert.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

1 Description

The Hoffmann II External Fixation system is a modular, multiplanar external fixation system used to stabilize open and/or unstable fractures and it can be used where soft tissue injury may preclude the use of other fracture treatments such as intramedullary nailing, casts or other means of internal fixation.

The system allows for independent pin implantation near the fracture site and subsequent building of the fixation frame around the pins.

Items part of the Hoffmann II System are: posts, rods, tubes, couplings, pin clamps, pin guides, pin drivers, lengtheners, adjustment instrumentation, and trays and tray accessories.

Different types of rods are available: straight connecting rods and semi-circular rods. Both straight and semi-circular rods are available in different lengths, diameters and materials.

Sterile field kits with pre-sterilized components and instruments are also available.

2 Intended Purpose

The Hoffmann II External Fixation System consists of a system of clamps, couplings and used to provide stabilization of open and/or unstable fractures of the tibia, femur, humerus, radius or pelvis, and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation.

3 Indications

The Hoffmann II External Fixation System is intended to be used in the stabilization of open and/or unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

The indications for use of metallic externall fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

4 Contraindications

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.

Conditions presenting an increased risk of failure include:

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.
- Previous history of infections.
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Malignancy in the fracture area.
- Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen.

5 Warnings and Precautions

Always consult the relevant operative techniques for additional information regarding each operative step.

⚠WARNING

- Do not use components of Stryker product systems together with components from any other manufacturer.
- Ensure that you are familiar with the intended uses, indications/contraindications, compatibility and correct handling of the devices, which are described in the operative technique manual for the product system.
- The licensed healthcare professional and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants to be applied. Complete information on these subjects must be readily available at the workplace.
- Single-use devices cannot be reused, as they are not designed to perform as intended after the first usage. Mechanical, physical or chemical properties may be compromised after first usage. In this case, the safety and performance of the devices is not supported by the manufacturer, compliance to relevant specifications cannot be ensured. External fixator devices have been designed for single patient use. Reuse of single-use external fixators may lead to reduced biomechanical properties and/or fatigue breakage of the devices. Do not reuse single-use external fixator components.
- Always treat the instruments and devices carefully to avoid surface damage or alterations to their geometry. Damage to the devices can significantly reduce the strength and fatigue resistance of the devices.
- Always exercise care in selecting the proper type and size of implant. Improper selection, placement and fixation of the implant components may result in early implant failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct-sized appliance for a given patient should be utilized. This can be determined by evaluating the patient's height, weight, functional demands and anatomy. The appliance should be used in the correct anatomic location, consistent with accepted standards of external fixation.

5.1 Pre-Operative

⚠WARNING

- Before every operation, ensure that all devices to be used during the operation function correctly with each other.
- Inspection is recommended prior surgery to determine if product have been damaged during storage.

5.2 Intra-Operative

⚠CAUTION

- While rare, intra-operative breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to breakage. Instruments should be examined for wear or damage prior to surgery and use.

5.3 Post-Operative

⚠WARNING

- These devices are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important.
- The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.

6 Magnetic Resonance Imaging (MRI) Information

⚠WARNING

The Hoffmann II System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Hoffmann II System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

7 Informing the Patient

⚠WARNING

- The licensed healthcare professional must instruct the patient to report any unusual changes of the operated site to their physician. The licensed healthcare professional should immediately evaluate the patient if a change at the fracture site has been detected. The licensed healthcare professional should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for reduced activity levels, and/or possible revision surgery in order to aid fracture healing.
- The licensed healthcare professional should discuss all physical and psychological limitations inherent in the use of external fracture fixation appliances with the patient. Particular attention should be given to premature weight bearing, activity levels and the necessity for periodic medical follow-up.

⚠CAUTION

- The licensed healthcare professional must inform patients of surgical risks, and make them aware of possible adverse effects.

The external fixator affects the patient's ability to carry loads and her/his mobility and general living circumstances. For this reason, the licensed healthcare professional must counsel each patient individually on correct behavior and activity after the implantation.

Explain the need to report unusual changes in the injured area as well as falls or accidents even if the device or the site of operation did not appear to be harmed at the time.

Explain also the need to appear for the postoperative examinations (e.g. X-ray checks) and for the removal of the external fixator.

8 Adverse Events and Adverse Effects

In many instances, adverse results may be clinically related rather than device related.

1. These devices can break when subjected to the increased loading associated with-delayed unions and/or nonunions. External fixation devices are load sharing devices which are intended to hold fractured bone surfaces in apposition to facilitate healing. If healing is delayed, or does not occur, the appliance may eventually break due to fatigue. Loads on the device produced by load bearing, and the patient's activity level, will dictate the longevity of the appliance.
2. Conditions attributable to nonunion, osteoporosis, osteomalacia, diabetes, inhibited revascularization and poor bone formation can cause: loosening, bending, cracking, fracture of the device or premature loss of fixation with the bone.
3. Delayed union or nonunion of the fracture site
4. Improper alignment can cause a malunion and/or bending or fracture of the device
5. Early or late infection, both deep or superficial
6. Deep venous thrombosis
7. Avascular necrosis
8. Shortening of the affected bone/fracture site
9. Subclinical nerve damage may possibly occur as a result of the surgical trauma
10. Metal sensitivity reactions in patients treated with external fixation devices have rarely been reported, and their significance awaits further clinical evaluation.

9 Sterility, Cleaning and Sterilization

⚠WARNING

- The packaging of all sterile products should be inspected for flaws in the sterile barrier or expiration of shelf life before opening. In the presence of such a flaw or expiration of shelf life, the product must be assumed non-sterile. Care must be taken to prevent contamination of the component.
- Products not labelled as sterile are non-sterile.
- In the event of contamination, or expiration of shelf life or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use, unless specified otherwise in the product labeling or respective product technical guides.
- Reusable Instruments must be cleaned directly after usage.
- For adequate cleaning of multi-component systems, these must be dismantled according to the assembly/disassembly instructions provided by Stryker.

The following process parameters are validated by Stryker and recommended for sterilization and/or resterilization, but not suitable for prion inactivation though:

Method:	Moist heat sterilization according to EN ISO 17665 and ANSI/AAMI ST79
Cycle:	Pre-Vacuum (Pre-Vac)
Temperature:	270°F (132 °C)
Exposure Time:	4 minutes
Drying Time:	30 minutes (minimum, in chamber)
Cool Time:	60 minutes (minimum, at room temperature)

NOTICE

Not for prion inactivation. Proceed according to local or national guidelines.

For more information regarding the cleaning and sterilization of these instruments please refer to the Stryker “Instructions for Cleaning, Sterilization, Inspection and Maintenance” (OT-RG-1) which may be requested online at www.ifu.stryker.com.

Where appropriate, reusable devices shall be placed in the compatible tray for sterilization according the process parameters provided below.

Where appropriate the cleaned, disinfected, and checked medical devices should be assembled into the dedicated trays provided. Stryker Trauma & Extremities cases/trays should be double wrapped. In the USA, Stryker Trauma & Extremities recommends compliance with ANSI/AAMI ST79 and the use of FDA cleared sterilization wrap. Please use a suitable instrument spray on articulating surfaces and moving parts.

Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations. The Instructions for Cleaning, Sterilization, Inspection and Maintenance (OT-RG-1) may be requested online at www.stryker.com or www.ifu.stryker.com.

10 Notification

Please inform the manufacturer, if a product related incident has occurred while using this device.

11 Transport and Storage Information

The device is individually packed in protective packaging that is labelled according to its contents. Store and transport the device in the original protective packaging or the appropriately marked storage module/tray. Do not remove the device from the packaging until it is planned to be used or it is ready to be placed in the storage module/tray. Store the devices in standard hospital environmental conditions (cool and dry) unless specific requirements are defined and described on the product label.

12 Special Training

The healthcare professional must be licensed to perform surgery in the respective field of medicine and must be familiar with the principles of the surgical procedure. No mandatory training is required for the intended user group before using the devices of the Hoffmann II External Fixation system.

13 For Further Information

Ensure that you are familiar with the intended purposes, indications/contraindications, compatibility and correct handling of the external fixator components which are described in the operative technique manual for the product system. Please remember that product systems may be subject to alterations that affect the compatibility of the implant with other implants or with instruments. For your information, avail yourself of the training courses and publications offered (e.g. operative techniques).

Important information for doctors and OR staff: This package insert does not include all of the information necessary for selection and use of a device. Please see full labeling for complete information!

- Instructions for Use, Operative Techniques, “Instructions for Cleaning, Sterilization, Inspection and Maintenance” (OT-RG-1), Patient Information Leaflets and other associated labeling may be requested online at www.ifu.stryker.com.
- The use of the system is described and/or illustrated in the operative technique of the product system. The applicable Operative Techniques for the external fixator components of the Hoffmann II External Fixation system can be found on www.ifu.stryker.com.
- For a symbol explanation please refer to the glossary OT-IFU-210 on www.ifu.stryker.com.
- Please contact Stryker or your authorized representative if further information on this product is needed.
- If the product does not function satisfactorily, please contact your local Stryker representative or call Stryker Customer Service.

14 Disposal

The hospitals should follow the national regulations in force for medical waste disposal.

Contaminated units should be decontaminated before they are discarded.

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