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MAR-03243, Version 1.0

Rx only

Instructions for Use

LINK Finger Splints

For U.S. Distribution Only
For further information please refer to the U.S. section of our website:

www.ifu-us.link-ortho.com

US DIST

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Legend of label symbols and descriptions

	Manufacturer
US DIST	U.S. Distributor
	Caution
	Consult instructions for use or consult electronic instructions for use
eifu.link-ortho.com	Consult instructions for use or consult electronic instructions for use
1	Single patient multiple use
Qty.	Number of units in the package
NON STERILE	Non-sterile
	Keep away from sunlight
	Date of manufacture (YYYY-MM-DD)
	Use-by date (YYYY-MM-DD)
	Fragile, handle with care
	Keep dry
	Do not use if package is damaged and consult instructions for use
REF	Article number
SN	Serial number
LOT	Batch number
MAT	Material Number
UDI	Unique device identifier
MD	Medical Device
ONR	Order number
	Date of manufacture
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
CE	Product fulfils the essential requirements of the Medical Device Regulation 2017/745
	Refer to instruction manual/booklet

Further information on the symbols glossary can be found on our website.

Instructions for Use

1. General

Please read this document carefully before using the system and keep it for future consultation!

This document does not contain all of the information necessary for the selection and application of the system. For safe and proper handling, refer to further product-related instructions, such as the packaging and the device labels on the packaging.

2. User Group

The intended users are physicians, medical staff, trained patients and trained third persons.

3. Patient Group

The patient group for our medical device is made up of all ages of any ethnic origin and of any gender where the size of the patient finger fits to the finger splint.

4. System Description

The LINK Finger Splints shall help to stabilize the distal interphalangeal (DIP) or the proximal interphalangeal (PIP) finger joint in an extension position.

The LINK Finger Splints promote the success of therapy for extensor tendon rupture through the automatic positioning of the distal finger joint in extension position and protects the fingertip and nail bed.

The LINK Finger Splints are available for two different finger joints. One model for the PIP joint and different models for the DIP joint. They all come in several colours as well as a padded version. Additionally, a thermoplastic moldable version is available for some models.

For fixation of the LINK Finger Splints special VELCRO Straps are available in different sizes.

An assortment box for The LINK Finger Splints and VELCRO Straps is also available. This assortment box provides clear storage of the finger splint.

5. Intended Use

The purpose of the finger splint is to enable the user to splint the finger in the event of an injury to the finger. Any other use of the finger splint is not permitted.

All finger splints are intended for temporary use.

The non-active, non-invasive finger splint manufactured by Waldemar Link GmbH & Co. KG is intended for long-term immobilization of a finger with uninjured skin with wound dressing of the human body. The finger splint supports, aligns or prevents unwanted movements of the finger during the healing process.

The splint can be fixed by medical staff, the trained patient or a trained third party.

The finger splint can be fixed with a VELCRO Strap.

The splints are supplied as single patient multiple use products.

6. Indications

	Extensor tendon rupture, fingertip and nail bed injuries	Buttonhole deformity (Boutonnière Deformity)
LINK Finger Splints Stack Type	x	–
LINK Finger Splints Stack Type Boutonnière	–	x
LINK Finger Splints Stack Type modified acc. to Drzezga	x	–
LINK STACTIP (STACTILE) Finger Splints Stack Type	x	–

7. Contraindications

- The finger splints are contra-indicated for any type of use beyond their intended uses. The finger splints may be used only by trained and qualified staff, trained patients and trained third parties.
- Material intolerance to the materials of the finger splint or strap
- Contact to injured skin

8. Possible Risks and Side Effects

- Skin complications
- Residual complaints
- Malalignment
- Instability, Dislocation

9. Clinical Benefit

The clinical benefit of the LINK Finger Splints is defined as:

- Restoration of joint functionality
- Reduction of extension lag

10. Materials

- Polyethylene, HDPE
- Polymethyl methacrylate, PMMA
- Needle fleece, white, with Ökotex fiber

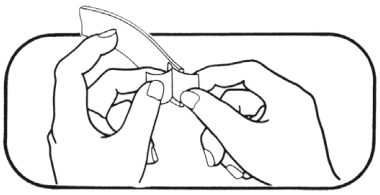
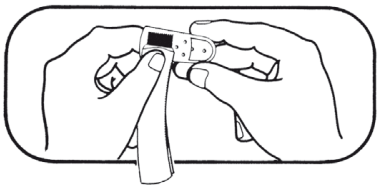
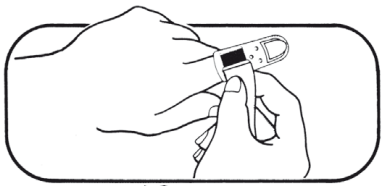
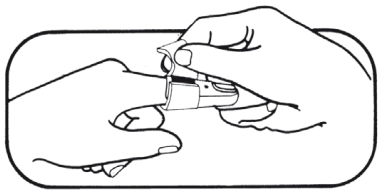
11. Duration of Application

The duration of application depends on the course of recovery of the respective patient and is to be decided by the physician.

12. Warnings / Precautions

The LINK Finger Splints and VELCRO Straps should not come into contact with open wounds. LINK Finger Splints and VELCRO Straps must be handled with great care and should not be modified or changed. Damaged Finger Splints or VELCRO Straps are not permitted to be used. Do not manipulate or misuse LINK Finger Splints and VELCRO Straps. We do not accept liability for products that have been modified, subjected to unintended use, or used improperly.

13. Fitting the finger splint using VELCRO Strap

	1. Remove the paper from the adhesive surface of the hooked side.
	2. Press the adhesive surface of the strap onto the finger splint.
	3. Press the loop side of the strap onto the hook side and slide the finger splint onto the injured finger.
	4. Wrap the strap tightly around the finger and press the loop side of the strap onto the hook side. Cut off the protruding part of the strap.

14. Removing

To remove the splint, remove the VELCRO Strap and pull the splint off cautiously.

15. Cleaning

Clean the finger splint thoroughly under running water (max. 50°C) and dry it well with a soft cloth.

16. Reprocessing / Reuse

The finger splints can be used multiple times on a single patient.

17. Information for Patient Advisory

The patients should be instructed:

- that the finger splint should only be removed for cleaning purpose
- about how to remove, clean and fit the finger splint
- to contact the doctor immediately, if problems occur (an increase in symptoms, swellings skin changes, etc.)

18. Storage and Transportation

The LINK Finger Splints must be stored in the undamaged packaging with protection against damage due to impacts, frost, humidity, excessive heat, and direct sunlight.

Further information is available from the manufacturer upon request.

19. Disposal

Packaging and system components to be discarded must be handled in compliance with your national and local regulations for disposal.

20. Requests

Requests of any kind should be directed to Waldemar Link GmbH& Co. KG (see contact information in this document).

15. Complaints about our products

Send complaints of any kind to Waldemar Link at: complaints@linkbio.com.

When filing a complaint, always quote the name or REF number of the relevant component along with the LOT and SN number, your name and your contact address. Describe the reason for the complaint in brief.

22. Report of serious incidents

Any serious incident that occurs in relation to the device must be reported to the manufacturer and the authority responsible for your location.