

You have now had a surgical operation to treat your joint with the RegJoint™ implant. The RegJoint™ implant is manufactured of bioabsorbable poly-96L/4D-lactide copolymer fibre. It is a porous, disc like implant. The fibres in the RegJoint™ implant offer an attachment base for your connective tissue cells and the porous structure enhances the welfare of the neotissue. The RegJoint™ implant provides temporary support and guidance for the fibrotic tissue in-growth. It allows a gradual optimized replacement of the implant with fibrous tissue providing a flexible and durable pseudo joint. The RegJoint™ implant loses its initial strength during 15 to 24 weeks, with complete strength loss and resorption on average within 2–3 years, depending on the patient variables.

The RegJoint™ implant is only one part of your successful recovery. It is essential to support the recovery with the individual physiotherapy and proper follow-up of the rehabilitation instructions. Healing of soft tissues may take up to 12 weeks and full recovery after the surgical operation of the small joints may take up to 6 months.

Swelling, haematoma and stiffness of the operated joint are common findings after this kind of an operation. The swelling usually decreases in 4–6 weeks. Physiotherapy and manipulation of the joints improve mobility and decrease stiffness.

A short period of mild pain has been noticed in some patients between 6–12 or 18–24 months after the operation. This phenomenon is connected with the active resorption period of the implant and usually does not require any specific action or only some pain medication according to the need.

In some patients minor osteolytic changes that confine to joint surface areas can be detected in radiographs approximately 6 months after the operation. Osteolytic changes do not seem to progress or to cause any clinical signs, but it is in most cases merely a radiographic finding.

Any serious incident that has occurred in relation to the device should be reported to Scaffdex Oy and the competent authority of the Member State in which the patient and/or healthcare institution is established.

EXAMPLES OF REHABILITATION PROGRAMS

It is important to understand that physiotherapy is adjusted to the patient's individual and specific needs and these procedures may vary between the patients, countries and hospitals. Therefore, the locally adapted program may differ from the options introduced here and on the Scaffdex website (www.scaffdex.com).

Scaffdex Oy as a manufacturer of the RegJoint™ implant does not practice medicine nor recommend these or any other rehabilitation programs to a specific individual patient. These are informative examples and presented with videos on the website.

HAND



THUMB BASE JOINT (CMC I)

Summary of rehabilitation process

- ➔ Cast for a few days (1)
- ➔ Scar treatment (1)
- ➔ Use of orthosis for 4–6 weeks post-op (2)
- ➔ **Rehabilitation phase A** up to 8 weeks post-op (3)
- ➔ **Rehabilitation phase B** 8–10 weeks post-op (4, 5)
- ➔ **Rehabilitation phase C** 10–12 weeks post-op (6)

1 Cast for a few days. Treatment of scar starts after proper healing of the wound and may last up to 4 months. By massaging the scar and using a silicone plaster and/or scar cream or gel to treat the scar, you may prevent joint stiffness after sutures are removed and the wound is healed.



2 On the second or third post-operative day, the plaster is removed and an orthosis (e.g. Hexalite, neoprene or thermoplastic material) can be applied for 4–6 weeks. The thumb is in a neutral position, the IP joints and the wrist are free. If needed, the orthosis can be still applied after 6 weeks.



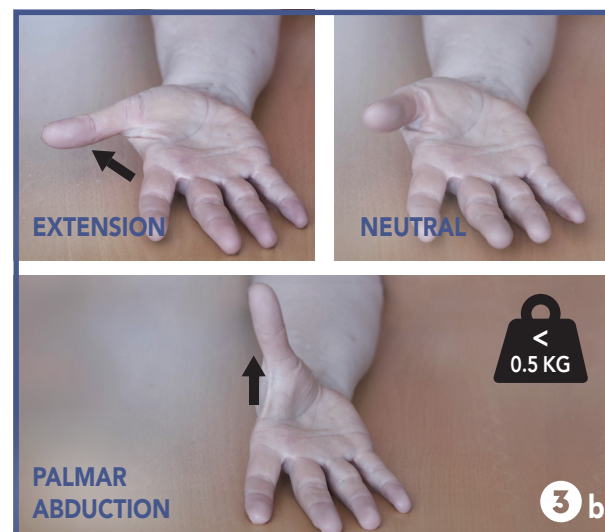
REHABILITATION PHASE A

3 Rehabilitation phase A 3–4 up to 8 weeks post-op. This can be started after the wound is properly healed and K-wire is removed. The reconstructive joint should be supported during exercises on the table with the palm facing up. Only light daily activities recommended, no loads exceeding 0.5 kg. Ice therapy and gentle massage help reduce swelling.

3a) Before training, preheat the joint with warm water or thermopack for 10 minutes.



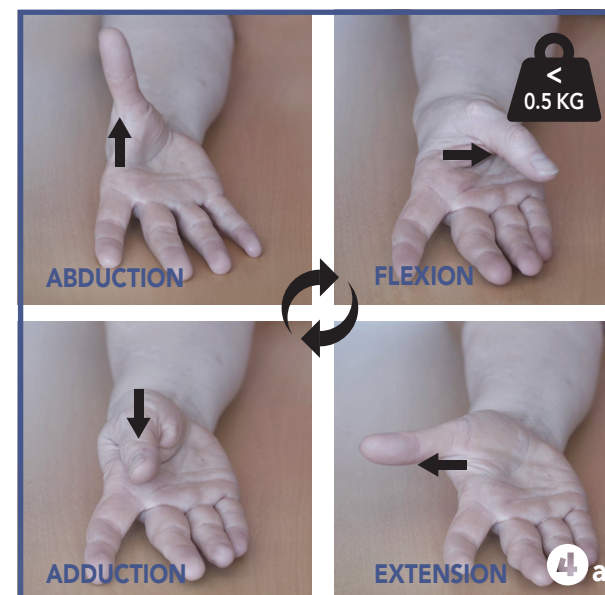
3b) Range of motion up to 8 weeks post-op. Exercises of extension and abduction, 20 times 3 times per day.



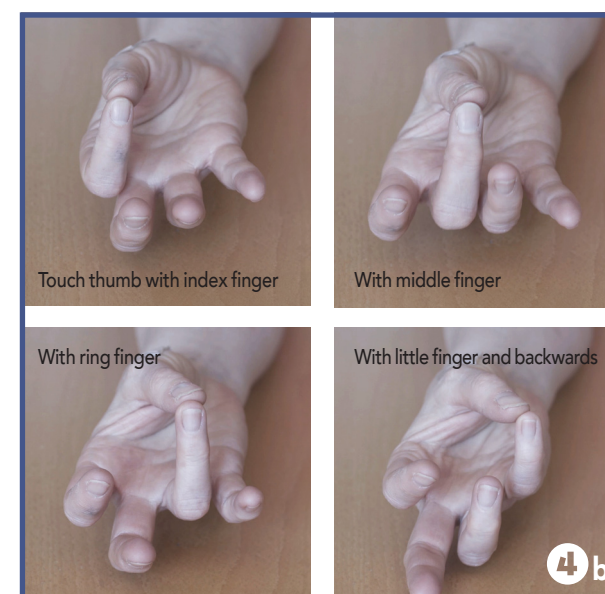
REHABILITATION PHASE B

4 Rehabilitation phase B 8–10 weeks post-op.

4a) Active range of motion, no loads exceeding 0.5 kg. Daily activities allowed. Training 10 times 3 times per day.



4b) Touch with your thumb all other fingers, 10 times 3 times per day.



5 Grip motion. Picking small light items, try small grip and still protect MCP joint. Daily activities allowed, but avoid pulling and carrying heavy bags using big forces. Grip motion training, 10 times 3 times per day.



REHABILITATION PHASE C

6 Rehabilitation phase C 10–12 weeks post-op.

Loads of 1 kg or more are allowed. Grip strength can be trained with heavier loads. Ball and light therapeutic putty can be used for strengthening the grip.



Magnetotherapy or electrostimulation can be used to decrease the pain, if needed.

METACARPOPHALANGEAL (MCP II–V) JOINTS

Summary of rehabilitation process

- ➔ Static cast for 7–10 days
- ➔ Dynamic cast for 12 weeks
- ➔ Passive training and cautious active training of fingers
- ➔ Light daily activities allowed with the dynamic cast

Watch rehabilitation videos online:

(scroll to the bottom of the webpage)



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FOOT

BIG TOE JOINT (MTP I)

Summary of rehabilitation process

- ➔ Walk only what is necessary 2 weeks post-op
- ➔ Keep your foot elevated always when resting
- ➔ Walk what is possible 2–6 weeks post-op
- ➔ Use therapeutic shoe until 6 weeks post-op
- ➔ Removal of sutures and/or K-wire 2–6 weeks post-op
- ➔ Use normal shoes but no high-heels 6–12 weeks post-op
- ➔ **Rehabilitation phase A 6–12 weeks post-op (1)**
- ➔ **Rehabilitation phase B after 12 weeks post-op (2)**

For the first 2 weeks after surgery, walk only necessary short distances for example for toilet and meals. RICE (rest, ice, compression, elevation) and taking NSAID (non-steroidal anti-inflammatory drugs) regularly is recommended. Keep your foot elevated always when you rest, the foot should be down only when walking. Use crutches if needed.

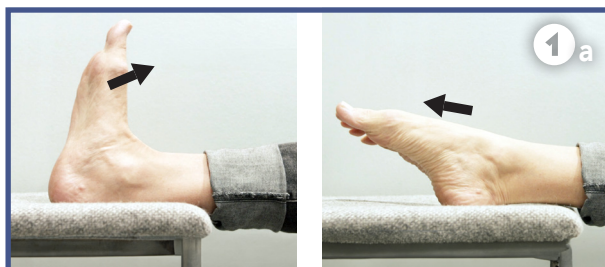
For 2–6 weeks post-op, walk what is possible. Preferably wear a roller bottom soft sole bandage shoe. If the therapeutic shoe has an off-loading sole with a big corner, be careful with correct walking and do not roll over the corner.

After 6 weeks post-op, start with Rehabilitation phase A.

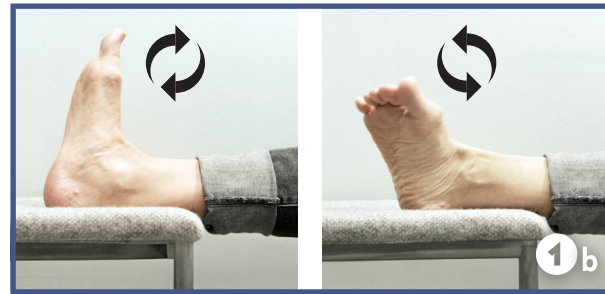
REHABILITATION PHASE A

1 Rehabilitation phase A 6–12 weeks post-op. In this phase, you can start using normal shoes (but not high-heels yet) and gradually increase the length of your walks. The operated foot should be elevated, for example, on a chair during exercises. Train different movements without extra loads.

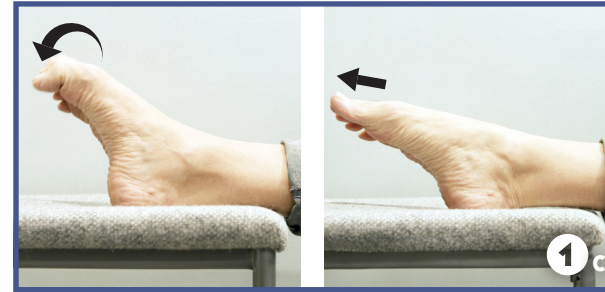
1a) Range of motion up to 12 weeks post-op. Exercises of straightening and bending your foot as far as possible, 10 times 3 times per day.



1b) Circle your ankle in both directions, 10 times 3 times per day.



1c) Straighten and bend your toes slowly as far as they go, 10 times 3 times per day.



REHABILITATION PHASE B



2 Rehabilitation phase B after 12 weeks post-op. The exercises should be done **sitting on a chair**, now training against the floor.

2a) Place your foot on the floor, lift up heel while keeping the toes on the floor. Repeat 10 times 3 times per day.



2b) Bend your toes against the floor and slide your foot against the floor, back and forth, 10 times 3 times per day.



If you have pain in your foot during or after this rehabilitation period, remember RICE (rest, ice, compression, elevation). Recovery after a surgical operation may take up to 6 months or even longer.

Watch rehabilitation videos online:

(scroll to the bottom of the webpage)



Individual rehabilitation program:

INSTRUCTION FOR COMPLETION

International implant card

- 1** Name of the patient or patient ID.
To be filled by the healthcare institution / provider.
- 2** Date of implantation.
To be filled by the healthcare institution / provider.
- 3** Name and address of the healthcare institution / provider.
To be filled by the healthcare institution / provider.

RegJoint™

International implant card
PATIENT



1. *Jane Smith*



2. *14/02/2025*



www.scaffdex.com

HEALTHCARE INSTITUTION



3. *Healthcare center*
Hospital road 1
12345 Towncity, Funland
Dr. A.B. Professional



Patient identification



Date



Healthcare institution / provider



Patient information website



Unique device identifier



Medical device



Manufacturer



Batch code



Serial number



Catalogue number



MR safe

scaffdex



Scaffdex Oy
Näsilinnankatu 48 E, 4th floor
FI-33200 Tampere, FINLAND
e-mail: orders@scaffdex.com
www.scaffdex.com