

You have had now a surgical operation to treat your joint with our RegJoint™ implant. RegJoint™ 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 neo tissue. RegJoint™ 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. RegJoint™ 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.

RegJoint™ implant is only one part of your successful recovery, which is essential to support 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 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 is established.

EXAMPLES OF REHABILITATION PROGRAMS

It is important to understand that physiotherapy is adjusted for 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 in 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 also with videos in website www.scaffdex.com.

HAND

Thumb base joint (CMC1)

1. Cast for few days



After removal of sutures and healing of the wound, massage and treatment of the scar with silicone plaster and / or scar cream or gel for avoidance of stiffness of the joint. This may last 2-4 months post-op.

2. Removal of K-wire in 3-4 weeks, if used



3. On the second or third post-operative day the plaster is removed and an orthose (e.g. Hexalite, neoprene or thermoplastic material) can be applied for 4- 6 weeks, thumb is in neutral position, IP and wrist free. After 6 weeks the orthose is applied if needed.

4. Rehabilitation phase A begins when the wound is properly healed and K-wire is removed, started in 3-4 weeks and applied up to 8 weeks.

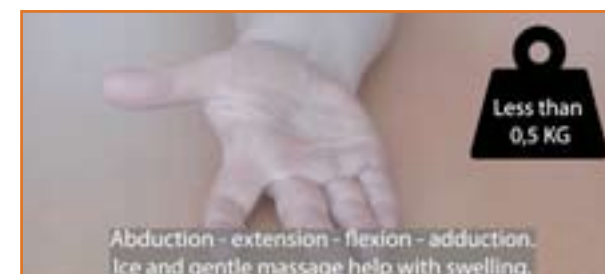
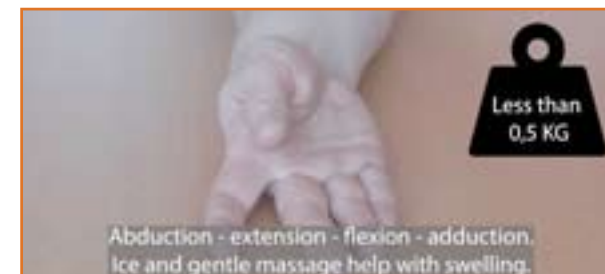
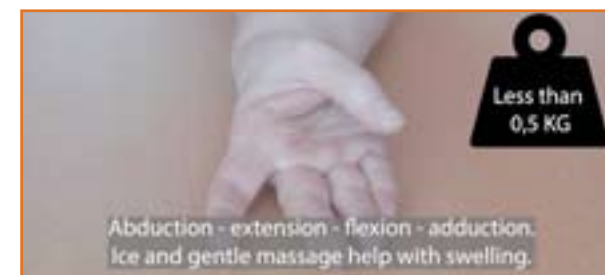


a. Warm-up the joint with warm water or thermopack for 10 minutes



MCP joint should be straight. No loads exceeding 0.5 kg, only light daily activities recommended.

5. Ice therapy and gentle massage help with swelling
6. Rehabilitation phase B begins in 8 - 10 weeks



a. Active range of motion



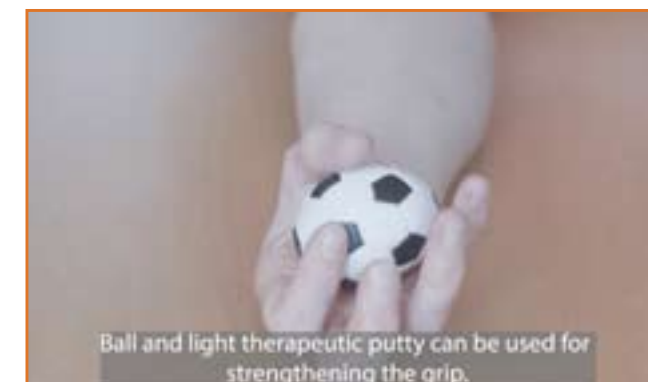
Grip motion



- b. Picking small light items
- c. Daily activities allowed, but no pulling, no heavy bags, no big forces
- d. No loads over 1 kg
- e. Grip strength can be trained with light loads, for example with therapeutic putty of light resistance level

7. Rehabilitation phase C in 10 – 12 weeks

- a. Loads of 1 kg or more is allowed now
- b. Grip strength can be trained with heavier loads now



c. Grip the ball, catch something

8. Magnetotherapy or electrostimulation can be used for decrease the pain, if needed Metacarpophalangeal joints (MCP)
1. Static cast for 7 – 10 days
2. Dynamic cast for 12 weeks
3. Passive training and cautious active training of fingers
4. Light daily activities allowed with the dynamic cast

FOOT

Big toe (MTP 1)

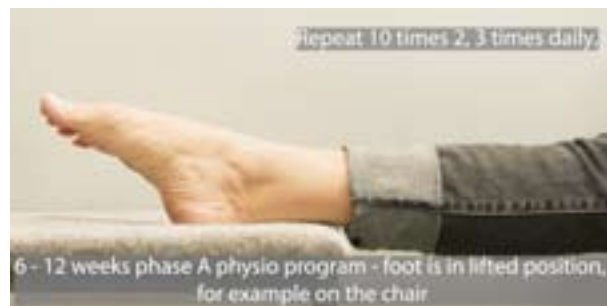
For the first 2 weeks post-op walk only what is necessary, like for toilet and meals. RICE (rest, ice, compression, elevation) is recommended and take regularly NSAID (non-steroidal anti-inflammatory drugs). Use crutches only when needed.

Preferably wear roller bottom soft sole bandage shoe. If the therapeutic shoe has an aggressively designed off-loading sole with a big corner, be careful with correct walking and do not roll over the corner.

2-6 weeks keep your foot up always when you rest. Keep your foot down only when walking. Sutures and/or K-wire are removed, if needed, in this phase.

Walk what is possible. 6-12 weeks post op you can start using normal shoes, but no high heels yet. Walk as much as what is convenient for you. In this phase you can start phase A physio program. Keep your foot in lifted position, for example on a chair and train different movements without extra loads.

Repeat this program A 2-3 times per day.



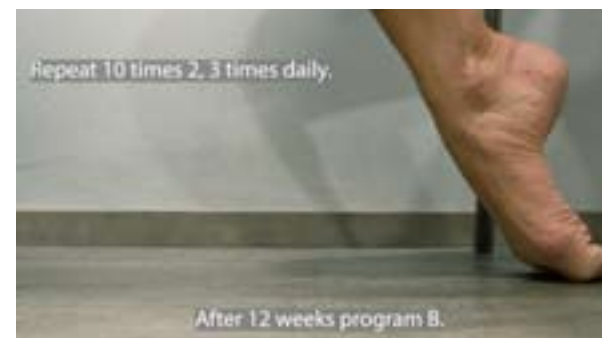
Straighten and bend your foot as far as possible 10 times.



Circle your ankle in both directions 10 times.



Bend and straighten your toes as far as possible 10 times.
After 12 weeks you can start Phase B physio program, still seated on a chair, but training against floor.



Bending of toes against the floor and sliding your foot against the floor, both directions 10 times. Repeat this program 2-3 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 6 months or even longer.

International implant card

Instruction for completion:

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.

INTERNATIONAL IMPLANT CARD
PATIENT

1. _____

2. _____

www.scaffdex.com

HEALTHCARE INSTITUTION



en Patient name



en Implant Date



en Healthcare institution



en Patient Information website



en Unique device identifier



en Medical device



en manufacturer



en batch number



en Serial number



en Catalogue number



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