Mikai Traction system – Instructions for Use and Warnings CE

EN

DESCRIPTION
The traction system is a class I medical device and is intended for use in orthopedics and wrist surgery in the treatment of distal radius fractures with dorsal or volar synthesis, in cases of ligament injuries and for wrist arthroscopy.
It is possible to realize an horizontal or vertical assembly, based on the indications. Eccentric with respect to the wrist in the two orthogonal planes, it allows a quickly passage from vertical to horizontal position and vice versa. The system allows for procedures of even complex interventions, to be performed without assistance in limb traction.
The traction system includes:
- A load bearing structure consisting of a system base, bar, wrist support, pin, traction bar and dynamometer
- 2 velcro bands of different lengths: 450 and 550 mm
- 3 stainless steel finger traps with different sizes (Small/Medium/Large)
- 3 autoclavable finger traps in polyethylene terephtalate with different sizes (Small/Medium/Large)

The different sizes and constituen materials of the finger traps allow them to be used for a large variety of patiens.

MATERIALS
Mikai traction system may feature the following construction materials:
Stainless steel: AISI 303, AISI 304, AISI 316L.
Aluminium: 6082, 7012.
Acetal resin.
Nylon and polyester.
Polyethylene terephthalate.
Mikai system has not been tested for use in MRI environment and should not be used under any circumstances in areas with strong electromagnetic fields such as in the case of MRI.

INDICATIONS FOR USE
The traction system device is indicated for:
- Wrist and hand traumatology
- Tendon and ligament injuries
- Reconstrunctions of the triangular fibrocartilage or the interosseous membrane
- Wrist arthrodesis
- Corrective osteotomies
- Wrist and hand prosthetics.

CONTRAINDICATIONS
The codes 500302P, 500304P and 500306P may contain latex. It is possible to replace them equivalent steel codes (500302A, 500304A and 500306A).

SURGICAL TECHNIQUE
Hereby are indicated the installation phases of the traction system in the horizontal and vertical configuration.

Vertical configuration:
1. With the elbow flexed at 90°, place the forearm on the base of the system.
2. Insert the bar (assembly of two components by screwing) and the wrist support in the specific holes, then, by acting on the knobs, proceed with locking.
3. Insert the band into the slots and lock the arm. Apply the traction rod on the bar. It is possible, if necessary, to use the extension bar.
4. Insert the splined bar and the dynamometer.
5. Apply the fingers traps, usually on the index or the ring finger, or on other fingers, depending on your needs.
6. To increase the wrist stability during the surgical procedure, a variable height extension can be applied to the existing support.
7. The position of the splined bar and the dynamometer can vary according to needs.
8. The use of polyethylene finger traps allows greater adaptability to the various sizes of the fingers.

Horizontal configuration:
1. Place and lock the clamp on the operating room table on the side where the surgeon will perform the surgery.
2. Insert the bar in the specific holes of the clamps and lock it by acting on the specific knob.
3. Apply the traction pin on the bar and then lock it.
4. Insert the splined bar and the dynamometer, locking them on the appropriate knob. Insert the fingers into the finger traps.

RECOMMENDATIONS AND PRECAUTIONS
Pre- Surgery
- The use of orthopaedic devices presumes an in-depth knowledge of the same and of the implant technique.
- If the surgeon should not be informed on the techniques related to this type of device it is advisable to consult the scientific and technical documentation on methodologies and devices in order to correctly assess possible risks.
- Contact the manufacturer for get information on indications, implant techniques, implant choice and risks or hazards.
- For the correct use of the system under discussion comply with the following provisions:
  - The device must be sterile.
  - It must not be used in conjunction with other instruments from different manufacturers.
  - The system must follow adequate operating techniques in suitable conditions.
- The choice, correct positioning, surgical technique, and instruments are critical factors in conditioning the success of the implant and post-op therapy.
- It is necessary to check the overall physical, superficial and functional integrity of the system before proceeding with their use.
- It is of fundamental importance to observe all the information, warnings, indications and contraindications, precautions described in the instructions for using the device.
- Store the product so that the packaging is not damaged or altered and do not use it if the packaging (container) is damaged.
- Proceed before each surgery with the disinfection and sterilization of the system.

Intra- Surgery
- Intra-operative system components failures may occur.
- The device must be used in a sterile environment.
- Mikai's own accessories must always be used and approved by the.
- Never, for any reason whatsoever, use damaged components of the system.
- Excessive or marked deformation of a device can cause a marked reduction in fatigue resistance.
- Care must be taken not to cut surgical gloves during the procedure.

Post- Surgery
- Do not use system components with products from other manufacturers unless otherwise indicated, as combined use is not covered by the required validation.
- Proceed after each surgery with the disinfection and sterilization of the system.

IMPORTANT
With respect to the wear/functioning state of the given instrument set, it is referred to the competence/experience of the user its corresponding evaluation.

NON-IMPLANTABLE DEVICE*
Mikai's traction system is non-implantable* and therefore should not be mounted on the device and/or the patient.
* Implantable device - Any device that has been designed to be totally or partially introduced into the human body through surgery and to remain in place after the procedure for at least 30 days is considered an implantable device.

CLEANING AND DISINFECTION
The traction system, with its accessories and sterilization tray must be cleaned, disinfected and sterilized before and after each use.
The cleaning and disinfection of Mikai traction system must be carried out by hand and with an ultrasonic washing machine, always wearing personal protective equipment; the parameters for each methodology are shown below:

	Manual cleaning	Ultrasonic cleaning
Active component	Enzymatic disinfectant - 0.3%	Phenol - 0.5%

Manual cleaning:
1. Fill a tank (tray capable of containing enough detergent to immerse the equipment to be washed) with a 0.3% enzymatic detergent solution at 40 ° C. DO NOT USE detergents with fluoride, chloride, bromide, iodide or hydroxyl ions.
2. Immerse the components to be washed taking care to release all the trapped air, leave the components immersed for 60 minutes in the solution.
3. Brush, shake, irrigate, jet wash or spray the elements to loosen and remove all visible dirt, perform all operations below the surface of the solution.
4. Remove the elements from the solution, drain and remove the residues with a brush under running water.
5. Immerse in sterile distilled water to remove any traces of running water.
6. Drain and hand dry with a clean, lint-free, disposable absorbent cloth, then dry in the drying cabin.
7. Fill in the required documentation and proceed with disinfection.

Ultrasonic disinfection:
1. Fill the tank of the ultrasonic cleaning machine to a level sufficient to ensure complete immersion of the elements, use a 0.5% phenolic disinfectant solution at an ultrasonic frequency of 50/60 Hz. DO NOT USE detergents with ions fluoride, chloride, bromide, iodide or hydroxyl.
2. Turn on the machine and wait all the time necessary to degas the water. Then remove the lid and immerse the element in the fluid, checking that the air contained in it is allowed to flow out. Flush cannulated devices. Put the lid back on and wait for the recommended amount of time (15 minutes).
3. Switch off the machine, remove the components and let them drip before transferring them to the wash / rinse container.
4. Rinse thoroughly with clean water, ensuring the irrigation of devices with openings and allow to drain, dry by hand with a clean, disposable non-lint-free absorbent cloth.
5. Fill in the required documentation and proceed with sterilization.

STERILIZATION
Devices are supplied exclusively NON-STERILE. The container and the traction system placed inside must be sterilized before being used in the operating room.
NON-STERILE system must be steam sterilized in an autoclave (according to the UNI EN ISO 17664 standard):

Procedure	Fractionated and dynamic pre-vacuum process
Exposure time	≥ 5 min
Temperature	134°C

	Name and full address of the manufacturer		See instructions for use
REF	Code	LOT	Lot No.

NON STERILE	Non sterile		Do not use if package is damaged
CE	CE marking		