

# Orthomed Silicone Hand (OM 49-0098)

## Instructions for Use

**ORTHO MED**  
The Surgical Instrument Specialists

**F-720-013**

Valid:  
May 13, 2024

Release  
M. Trone

Revision  
Initial Release

Page 1 of 1

**ORTHO MED**  
The Surgical Instrument Specialists

Orthomed, Inc  
14875 SW 72nd Ave.  
Tigard, OR 97224  
(503) 234-9691  
www.orthomedinc.com  
support@orthomedinc.com

### Important notice



Please read this product description carefully before each use.



Read the warnings marked with this symbol carefully. Improper use of the products may result in serious injury to the patient, users or third parties.

### Silicone hand



Individually bendable  
finger fixation

Individually bendable  
wrist fixation

### Ring

The silicone ring is a reusable component of the silicone hand, made of silicone, and is intended to be used as an elastic band to hold the fingers in place.

### Scope

This product description refers to the silicone hand.

This product description is  
It may not be reproduced or used  
without express authorization.



**This product description is  
for information only.**

**If these products are to be  
used in the medical field,  
the distributor or "legal  
manufacturer" is  
responsible for instructions  
for use for the subsequent  
applications and  
indications are responsible**

### Application Area

The reusable silicone hand is designed to ensure precise and stable positioning of the hand during surgery.

Collaboration with hand surgeons during development ensures that the silicone hand meets the requirements and needs of medical professionals.

### Safe handling and delivery

- The product and accessories should only be operated and used by persons who have the necessary training, knowledge and experience.
- Read, observe and retain the product description.
- Use the product only for its intended purpose.
- Store new or unused product in a dry, clean and protected place.

### Life cycle

The silicone hand can be reused many times, but its life is limited.

After 450 bends or applications, the silicone hand must be disposed of in accordance with local national regulations. Otherwise there is a risk of material fatigue.

### Warning notice

It is important not to use the silicone hand immediately after sterilisation in a warm state, as this can lead to faster wear. Please allow the Silicone Hand to cool to room temperature before use to prolong its life.

Do not store the silicone hand near corrosive products such as chlorine. These substances can damage the silicone and shorten its life. Store the silicone hand in a safe place away from corrosive products.



**Ensure that the silicone  
hand has been properly  
cleaned and sterilized to  
minimize the risk of  
infection to the patient.**

### Cleaning/Disinfection

Product-specific safety instructions for the reprocessing procedure



**Damage to the product due to  
inappropriate  
cleaning/disinfecting agents  
and/or excessive temperatures!**

- Use detergents and disinfectants according to the manufacturer's instructions.
    - Approved for plastics.
    - Which do not attack softeners (e.g. in silicone).
  - Observe information on concentration, temperature and exposure time.
  - Do not exceed the maximum permissible cleaning temperature of 96°C.
  - For wet disposal, use suitable cleaning/disinfecting agents. To avoid foaming and deterioration of the effectiveness of the process chemicals: Before machine cleaning and disinfection, rinse product thoroughly with running water.
  - Carry out ultrasonic cleaning:
    - as effective mechanical support for manual cleaning/disinfection.
    - for the pre-cleaning of products with encrusted residues before machine cleaning/disinfection.
    - as integrated mechanical support for machine cleaning/disinfection.
    - for the post-cleaning of products with residues that have not been removed after machine cleaning/disinfection.
- ### Steam sterilization
- Ensure that the sterilizing agent has access to all external and internal surfaces (e.g. by unscrewing or uncoupling screw inserts, drills or other accessories).
  - Validated sterilization procedure
    - Steam sterilization in fractionated vacuum or gravitational process
    - Steam sterilizer according to DIN EN 285 and validated according to 17665
    - Sterilization in fractionated vacuum at 134 °C, holding time 5 min.
  - If several products are sterilized simultaneously in one steam sterilizer: Ensure that the maximum permissible load of the steam sterilizer is not exceeded according to the manufacturer's instructions.

### Disposal

Disposal or recycling of the product, its components, and packaging must be in accordance with local or national regulations.