

ACCESSORY MANUAL

R-SW Handpieces For ShockMaster devices



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1 General information

1.1 Introduction

This manual describes the use of the R-SW handpiece and R-SW handpiece Short, as assigned certain standard accessory for the ShockMaster control units distributed by:

GymnaUniphy NV
Pasweg 6A
3740 Bilzen
Belgium
Tel.: +32(0) 89 510.510
Fax: +32(0) 89 510.511
info@gymna.com
www.gymna.com

This manual contains warnings, safety instructions and specific operating instructions in accordance with liability regulations.



CAUTION

Complete or partial failure to observe the instructions, information or procedures preceded by the term "CAUTION" may cause injury or fatal accidents.



ATTENTION

Complete or partial failure to observe the instructions, information or procedures preceded by the term "ATTENTION" may cause equipment damage.

NOTE

Additional information concerning specific features or operating instructions is preceded by the term "NOTE"



CAUTION

Before using the R-SW handpiece for the first time, please make sure you have read and understood all information provided in this operating manual.

Familiarity with the information and instructions contained in this manual is essential for ensuring efficient and optimal use of the system, for avoiding hazards to personnel and equipment and for obtaining good treatment results.



Thorough knowledge of the information included in this manual will also enable you to react promptly and effectively in the event of malfunctions or failures

1.2 Symbols

It is essential to comply with the operating manual! Affixing location: on both sides of the handpiece shaft.

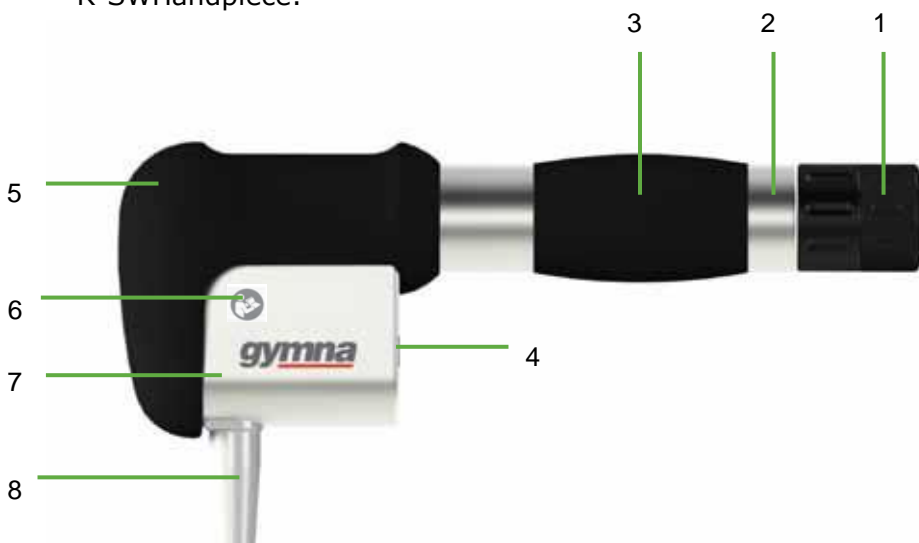


Replaces previous symbol



1.3 R-SW handpieces

R-SWHandpiece:

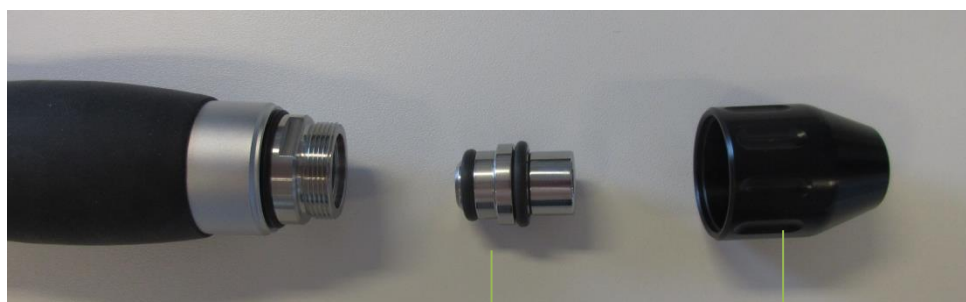


- 1. Applicator
- 2. Applicator screw cap
- 3. Handle
- 4. Trigger button
- 5. Protective cushion
- 6. Symbol "It is essential to comply with the operating manual!"
- 7. Handpiece handle
- 8. Connection cable

R-SW handpiece Short:



- 1. Applicator
- 2. Applicator screw cap
- 3. Handle
- 4. Trigger button
- 5. /
- 6. Symbol "It is essential to comply with the operating manual!"
- 7. Handpiece handle
- 8. Connection cable



1. applicator

2. applicator screw cap



NOTE
 Pictures of handpiece and applicator are examples. Individual components may differ from those shown in the illustration.

Depending on the therapy to be performed, the handpiece can be equipped with different shock transmitters/applicators:

- Beam applicator (1)
- Classic 15mm applicator (2)
- 6mm acupuncture applicator (3)
- D-Actor 20mm S (4)
- D-Actor 35mm S (5)
- Focus lens (6)
- Deep Impact applicator(7)
- Fascia applicator set (including adaptor) (8)*
- Spine applicator set (including adaptor) (9)*



* Only compatible with Handpiece Short

2 Installation instructions

2.1 Unpacking

Remove the equipment and accessories from the packaging container. Proceed with extreme caution.

Check that all items are included in the packaging container and that they are not damaged.

Contact your supplier or the manufacturer immediately if any items are missing or damaged.

Retain the original packaging. It may prove useful for any later equipment transport.

2.2 Scope of supply

The standard scope of supply of the R-SW handpieces includes the following items:

- ShockMaster R-SW Handpiece OR R-SW Handpiece Short (including 1 guide tube)
- ShockMaster Beam applicator Black
- ShockMaster D-Actor 20mm S Black
- ShockMaster Deep Impact applicator Black
- 2x metal projectile
- Guide Tube
- hexagon spanner 2.5 mm
- Open-end spanner
- Paper case with foam insert
- Cleaning brush, 7mm, 35cm

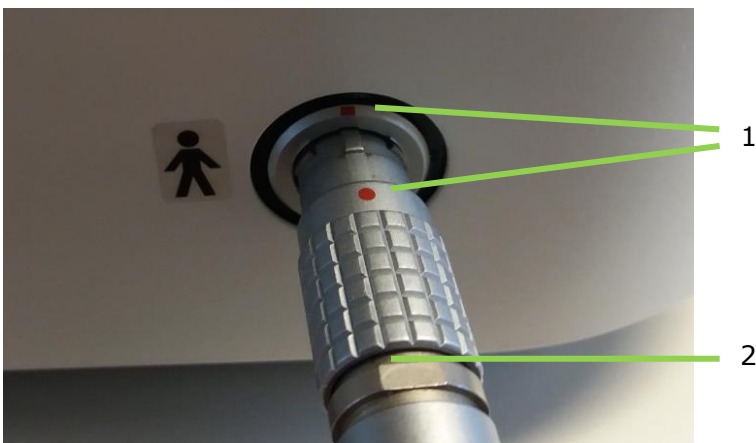
Please refer to Section 6 for information on ACCESSORIES AND SPARE PARTS.

2.3 Handpiece connection

NOTE

Please also refer to the separate operating instructions of your control unit

- Connect the plug of the ShockMaster R-SW handpiece to the handpiece connector provided on the respective control unit.
- Line up the red dots on the plug with the red dots on the connector before connecting. (1)



- Gently pushing the plug into the connector will immediately lock the access and will prevent the connector from disengaging automatically when the cable is pulled.
- Place the handpiece into the handpiece holder



- To break the connection, pull the outside of the plug body. This means the locking function is initially released, then the plug is pulled out of the handpiece connector. (2)

3 Operation

3.1 General warnings and safety information

See the user manual of the ShockMaster control unit.

NOTE

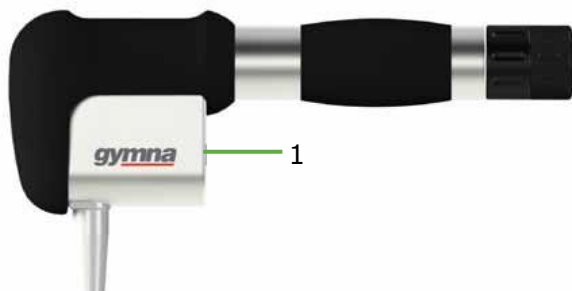
The R-SW handpieces are suitable to connect to the ShockMaster control units.

3.2 Start-up

NOTE

Prior to start-up, please refer to the separate operation manual of your control unit.

- Connect the R-SW handpiece (Short) to the control unit
- Set the pressure level to an initial value of 2 bar and 10Hz
- Activate the trigger button (1)



3.3 Functional checks

Perform the following functional checks after the system has been installed:

- Check the handpiece for possible damage.
- Perform the start-up (see Chapter 3.2 START-UP).
- Release individual shocks in single shock mode. (See operating manual for control unit.)
- Release shocks in continuous shock mode. (See operating manual for control unit.)

3.4 Treatment



CAUTION

Always read Chapter 3.1 SAFETY INSTRUCTIONS before beginning the treatment.

NOTE

The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.

- Apply a sufficient amount of coupling gel to the patient's skin in the treatment area when using shock transmitters.
- Fascia and Spine transmitters are "vibration"-therapy transmitters. Therefore, no contact gel is needed. In case of Spine actors, one can decide to use gel, just for easier contact movement.
- Do not apply more than 300-400 shocks to the same spot.
- Avoid pressing the applicator onto the treatment point with excessive pressure! Such pressure is not needed for successful treatment.
- Perform Radial Shockwave treatment as described in the application mode.

**CAUTION**

The applicator surface will become hot! Extended skin contact can lead to minor burns!

- Interrupt treatment after a maximum of 6000 shocks.

**CAUTION**

The handpiece may not be operated while idling (without an impact surface)

- Do not trigger pulses unless the applicator is in contact with the treatment zone!

**CAUTION**

We recommend that the user and the patient wear suitable hearing protection.

- Always offer the patient ear protection

**ATTENTION**

Spine and Fascia applicator set is only compatible with Handpiece Short

- Always use Handpiece Short when choosing Spine or Fascia applicators

**ATTENTION**

Maximum pressure is 3bar_{eff} when using the Spine or Fascia applicators

- Don't increase the pressure when 3bar_{eff} is reached with Spine and Fascia applicators

3.5 Replacing the applicator

Replace the applicator as described in Chapter 4.2 REPLACING THE APPLICATOR.

4 Cleaning, Maintenance and Overhaul

4.1 Cleaning



CAUTION

Flammable and volatile cleansing and disinfecting agents may generate an explosive atmosphere.

- Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

ATTENTION

It is essential that no fluid be permitted to penetrate either the unit or its tubing.

Regular cleaning of the system ensures perfect hygiene and operation of the ShockMaster R-SW handpiece (Short).

The handpiece, in particular the applicator, must be thoroughly cleaned and disinfected after each therapy session.

| Component | Procedure | Interval |
|------------------------------------|--|--|
| Handpiece shaft and cushion | Clean and disinfect | Daily or after 20.000 shocks |
| Guide tube | Use the cleaning brush to remove loose particles inside the tube | Every day |
| Applicators and O-rings | Clean in ultrasound bath and disinfect | After each treatment or contact with a patient |
| Guide tube, projectile and O-rings | Replace | After 1.250.000 shocks (revision of the handpiece) |

NOTE

The handpiece is equipped with a projectile safety catch device in order to prevent the projectile from being ejected in case a shock is released while the applicator and the applicator screw cap are removed.

The safety catch is also activated if the applicator screw cap is not screwed on tightly, if the sealing ring between the cap and the applicator is missing or if two sealing rings (old and new) come together at the rear of the applicator. If the projectile is caught by the safety catch, it can be pushed back into the guide tube using reasonable force. If this occurs repeatedly or if the projectile cannot be removed or if the receptory edge is damaged, then the handpiece shaft should be replaced completely in order to ensure proper function.

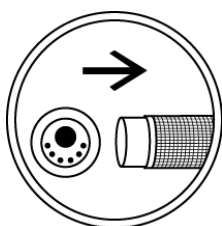
4.1.1 Cleaning the handpiece



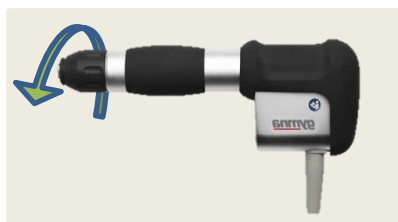
ATTENTION

After cleaning, the handpiece must be dry before it can be reassembled.

- For that reason, schedule sufficient time for the drying of the handpiece and its components.



1. Disconnect the handpiece from the control unit



2. Unscrew the applicator screw cap from the handpiece



3. Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning
4. Disinfect the handpiece with an alcohol based disinfectant that is suitable for surface cleaning



5. Unscrew the shaft from the handpiece. Use the open end wrench for this



6. Pull the shaft out of the handpiece handle. Clean the inside of the tube with the brush



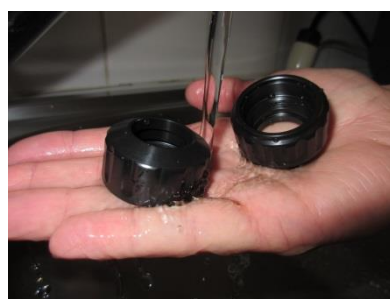
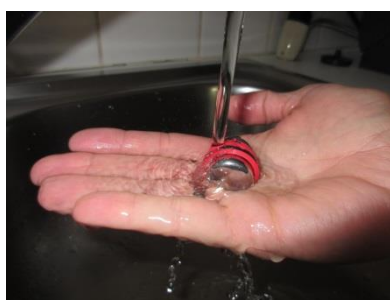
7. To clean the handpiece, the protective cushion can be pulled back and up off the handpiece handle (not needed for Handpiece Short)

4.1.2 Cleaning the applicators

- Unscrew the applicator screw cap and remove the applicator from the applicator screw cap.
- Clean all parts under running water



NOTE The applicator with the D-Actor 20mm and D-Actor 35-S can only be dismantled and the sealing rings can only be removed using special tools. You should avoid doing this because it could result in damage to the applicator. It is not necessary for cleaning purposes.



- It is also recommended that the applicator be cleaned and disinfected in an ultrasonic bath.
- For this purpose, use only instrument disinfectants for heat-sensitive, reusable medical devices.

4.2 Replacing the applicator

- Disconnect the R-SW handpiece from the control unit.
- Unscrew the single applicator screw cap (Beam, Classic 15mm, 6 mm Acupuncture, Deep Impact, Focus Lens or the double applicator screw cap (D-ACTOR I, D-ACTOR II, see picture page 15/ bottom) from the handpiece.
- Screw the two-piece applicator screw cap apart (D-ACTOR I and D-ACTOR II).
- Remove the applicator.
- Clean coupling gel and dust off the applicator screw cap and the applicator.
- Insert the applicator into the corresponding applicator screw cap.
- Screw the applicator screw cap onto the handpiece until fingertight
- For Fascia and Spine actors always first screw the adaptor on the R-SW handpiece Short and click the transmitter in the adaptor.

4.3 R-SW handpieces revision

Shock waves are generated mechanically. Due to the effects of friction, the R-SW handpiece components are continuously exposed to mechanical stress that will cause minor wear.



ATTENTION

The R-SW handpieces should be revised about every 1,250,000 shocks. This can be done quickly and easily by the equipment user. All that is required is the revision kit that includes all required wearing parts.



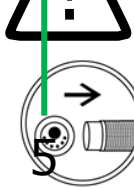
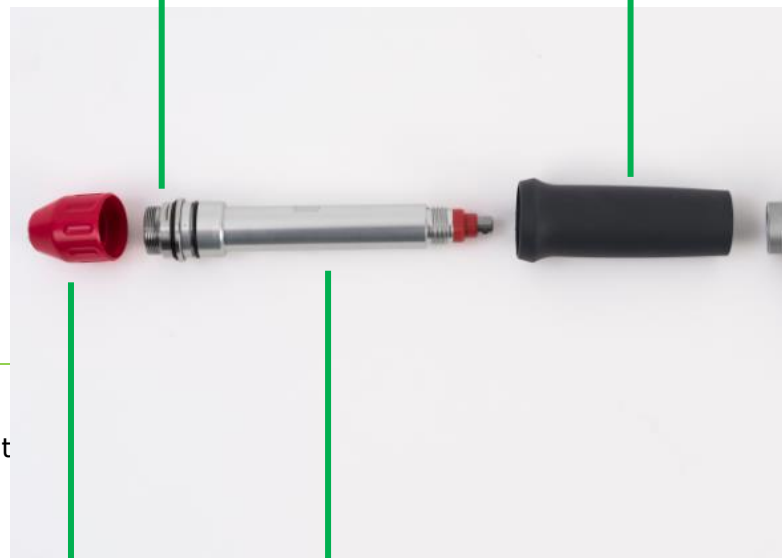
ATTENTION

The R-SW handpieces should be send back to the Service department for a complete revision after 5 million shocks (= after 3 revisions)

4.3.1 Contents of the ShockMaster revision kit

- Cardboard box with protective foam sheets 2 projectiles
- 2 guide tubes
- 2 socket sealing rings

The ShockMaster Revision kit 22591 Black is available under order number 309771.
The Revision kit Handpiece Short has order number 342705.



Danger of injury due to shock if connected.

- Disconnect the handpiece from the control unit before replacing the applicator

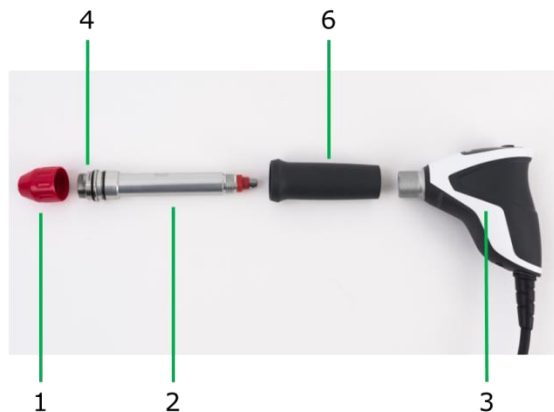
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2

- Pull the R-SW handpiece plug out of the handpiece connector of the control unit.
- Place the handpiece on a dry, clean and dust-free surface.
- Unscrew the applicator screw cap.
- Unscrew the shaft from the handpiece and pull it out of the handpiece handle. Use the supplied open-end spanner for this purpose.

ATTENTION

An open-ended wrench should be used for releasing the handpiece shaft for overhauling the handpiece



5

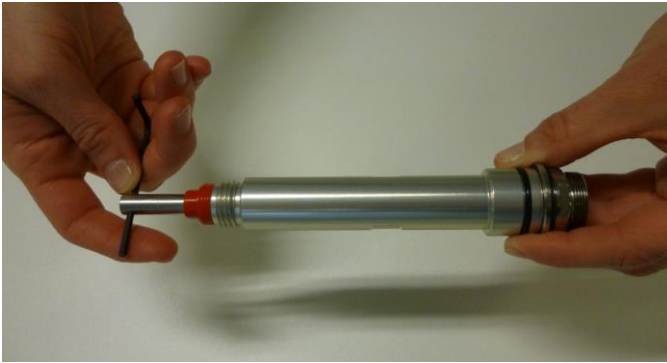
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2

3

1. Applicator
2. Handpiece shaft
3. Handpiece handle
4. Sealing ring
5. Fork wrench
6. Handle

- Remove the tightly fitting guide tube from the shaft. If necessary, use a thin metal rod or the supplied hexagon spanner as a pulling tool by inserting it through the openings in the guide tube.



- A corresponding fixture is provided in the handpiece handle to hold the projectile. To remove the projectile, hold the handpiece handle in such a way that it's opening points downwards. Slightly knock the handle against the table surface until the projectile falls out. In the event that the projectile breaks apart due to overloading, a fragment of the projectile may be left behind inside the guide tube.
- Dispose of the used guide tube and the used projectile.
- Clean the shaft, the applicator (including firmly seated sealing rings) and the applicator screw cap using a disinfectant containing alcohol. These are reused after cleaning.
- Make sure to place all cleaned components onto a clean, dry and dust free surface.
- Take out the new guide tube and the new projectile to be found in the overhaul kit.
- To replace the red sealing sleeve insert it into the shaft. Insert the guide tube into the opening in the shaft by pressing it until it hits the stop. Make sure that the end of the guide tube where the two air slots are located is in the direction of the handpiece handle.



- Insert the new projectile into the fitted guide tube.

NOTE

Both the projectile and the guide tube need to be replaced each time the handpiece is overhauled.


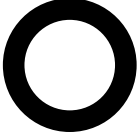
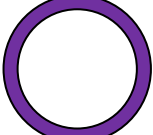
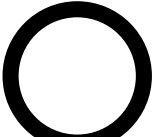
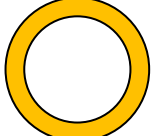

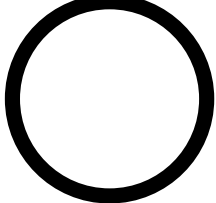
- Screw the shaft into the handpiece until fingertight.
- Using one hand, press the handpiece firmly onto the table and tighten the shaft using the open-end spanner. It must no longer be possible to unscrew the shaft by hand.

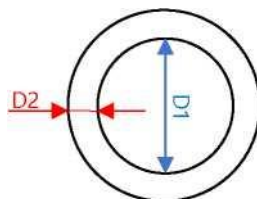


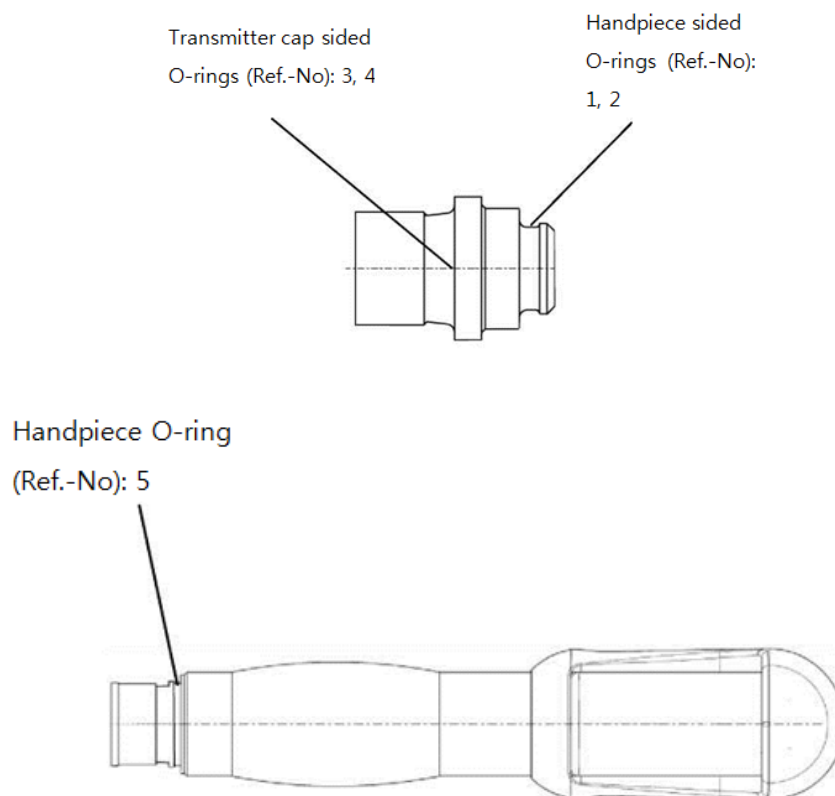
- Screw the applicator screw cap with the required applicator back onto the shaft.
- Carry out a functional check of the handpiece (see Chapter 3.3 FUNCTIONAL CHECKS).
- Reset the handpiece counter of the control unit (refer to the operating manual of your control unit).

4.3.3 O-ring guide

When performing a revision of the handpiece, check and replace the O-rings of the handpiece and applicators.

| Ref.- No | O-Ring (1:1) | Measurements | Used for |
|-------------|--|-------------------------|------------------------------------|
| 1 |  | D1=11.0 mm D2=3.0 mm | Beam Focus Lens Classic 15mm |
| 2 |  | D1=12.0 mm D2=2.5mm | Deep Impact |
| 3 |   | D1=14.5 mm D2=2.5 mm | Classic 15mm Deep Impact |
| 4 |   | D1=13.0 mm D2=3.0 mm | Beam Focus Lens |
| 5 |  | D1=24.0 mm D2=1.5 mm | handpiece |





4.4 Maintenance

Preventive maintenance is not necessarily required.

4.5 Disposal

No special measures need to be observed when disposing of the present medical products. Please proceed in accordance with applicable country-specific regulations. At the end of the service life of the handpiece, please return the device to GymnaUniphy.

4.6 Repair

Repair work on defective equipment must only be carried out by authorized personnel. Only original spare parts may be used for this purpose.

See the user manual of the ShockMaster control unit.

4.7 Service life

The Handpiece should be overhauled after around every 1.25 million shocks (see 4.3 R-SW handpiece revision).

Provided this interval is observed, the average expected service life is approximately 5 million shocks for the handpiece and 1 million shocks for the applicators.

The performance and reliability of the device may be compromised if:

- failure to perform a revision of the handpiece after 1.25 million shocks
- failure to perform service of the handpiece after 5 million shocks
- failure to change the applicator after 1 million shocks
- use of non-original spare parts

In such cases, no warranty claims shall be accepted on the basis of the information given in chapter 8 (Warranty).

For information about the service life of your control device, please refer to the separate operating manual for your control device.

5 Troubleshooting

| Fault description | Possible cause | Corrective action |
|---------------------------------|---|--|
| No shock wave power output | Leaks on handpiece cable or cable not properly connected. Blocked or worn projectile Handpiece defective No projectile Guide tube installed the wrong way round | Check the cable and tube connections and replace them if necessary Take handpiece apart Overhaul the handpiece Replace the handpiece Install projectile Turn the guide tube round |
| Irregular frequency | 2 projectiles | Remove one projectile |
| Leak on the handpiece connector | Defective or missing red O-ring on plug | Send in handpiece or inform Service |

6 Accessories and spare parts

6.1 R-SW handpieces

- Revision Kit 309771
- Revision Kit Handpiece Short 342705

NOTE

For information on various applicators, please contact your distributor

6.2 Documentation

Accessory Manual R-SW Handpiece

7 Technical specifications

7.1 R-SW handpiece Short

- Compressed air input
ShockMaster 500 0.3 - 5 bar_{eff}
ShockMaster 300 0.3 - 4 bar_{eff}
- Operating conditions
Ambient temperature: 10 °C - 40 °C
Atmospheric pressure: 70 - 106 kPa
Relative humidity: 5% - 55%, non-condensing
- Storage and transport conditions
Ambient temperature: °C - +60 °C
Atmospheric pressure: 50 - 106 kPa
Relative humidity: 5% - 95%, non-condensing
- Weight 450 g
- Classification according to
MDD 93/42/EEC: IIa
MDR SOR/98-282: II
- Applied parts type B

7.2 R-SW handpiece

- Compressed air input
ShockMaster 500 1 - 5 bar_{eff}
ShockMaster 300 1 - 4 bar_{eff}
- Operating conditions
Ambient temperature: 10 °C - 40 °C
Atmospheric pressure: 70 - 106 kPa
Relative humidity: 30% - 75%
- Storage and transport conditions
Ambient temperature: -20 °C - +60 °C
Atmospheric pressure: 50 - 106 kPa
Relative humidity: 5% - 90%, non-condensing
- Weight 450 g
- Classification according to
MDD 93/42/EEC: IIa
MDR SOR/98-282: II
- Applied parts type B

8 Warranty

8.1 Warranty

Both the R-SW handpiece and applicators are a wear and tear part. We will replace new handpieces that have performed up to 2 million pulses at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship. Transport costs and the risk of loss during the shipping of returned products shall be borne by the customer.

Warranty claims will only be accepted if the handpiece is returned in its complete and original state, cleaned and in the original packaging if at all possible (without applicator, without accessories). Missing components will be replaced subject to charge. Applicators and revision kits are not covered by the handpiece's warranty.



ATTENTION

Modifications on the handpiece and applicator are not permitted. Any unauthorized opening, repair or modification of the system by unauthorized personnel will relieve the manufacturer of its liability and responsibility for safe system operation. This will automatically void the warranty even before the end of the warranty period.

