

ACCESSORY MANUAL

RSW Handpieces

For ShockMaster devices



Table of Contents

1	General information	4
1.1	Introduction	4
1.2	Symbols.....	5
1.3	RSW handpieces	5
2	Installation instructions	8
2.1	Unpacking	8
2.2	Scope of supply.....	8
2.3	Assembling the handpiece	9
2.4	Handpiece connection	9
3	Operation	11
3.1	General warnings and safety information.....	11
3.2	Functional checks	11
3.3	Start-up	11
3.4	Treatment	12
3.5	Replacing the applicator	13
4	Cleaning, Maintenance and Overhaul.....	14
4.1	Cleaning.....	14
4.1.1	Cleaning the handpiece.....	15
4.1.2	Cleaning the applicators.....	16
4.2	RSW handpieces revision.....	17
4.2.1	Contents of the ShockMaster revision kit	17
4.2.2	Revision of the handpiece	18
4.2.3	O-ring guide.....	21
4.3	Maintenance	22
4.4	Disposal	22
4.5	Repair	22
4.6	Service life	23
5	Trouble-shooting	24
6	Accessories and spare parts	25
6.1	RSW handpieces	25
6.2	Documentation	25
7	Technical specifications	26
7.1	RSW handpiece Short	26
7.2	RSW handpiece	26
8	Warranty	27
8.1	Warranty.....	27

1 General information

1.1 Introduction

This manual describes the use of the RSW handpiece and RSW handpiece short, as assigned standard accessory for the ShockMaster control units distributed by:

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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 RSW 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.

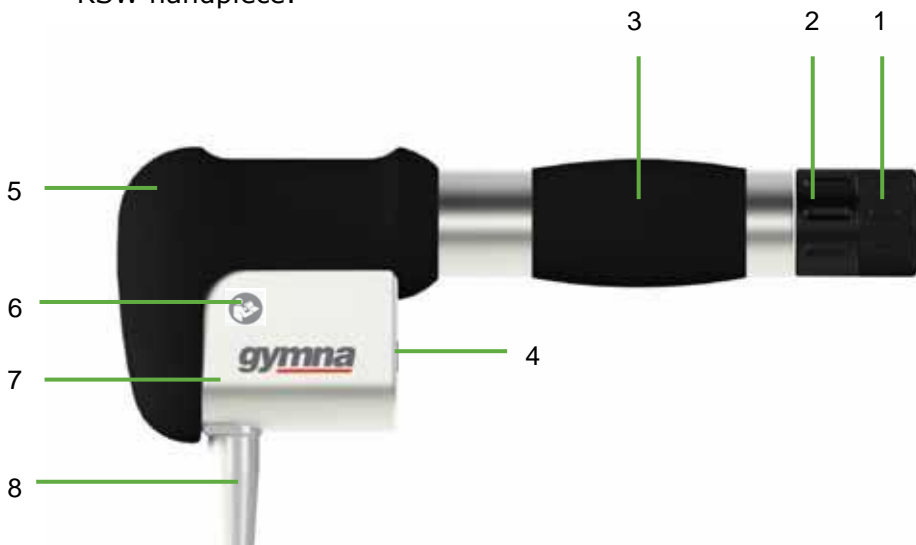


Replaces previous symbol



1.3 RSW handpieces

RSW handpiece:

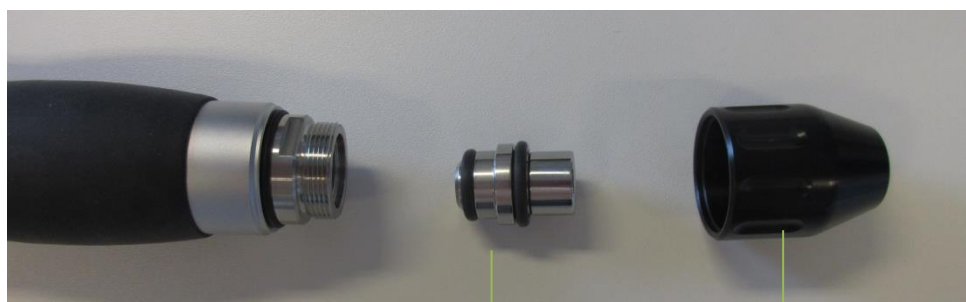


- 1. Applicator
- 2. Applicator screw cap
- 3. Handle
- 4. Trigger button
- 5. Protective cushion
- 6. Symbol "It is essential to comply with the operating manual!"
- 7. Handpiece handle
- 8. Connection cable

RSW 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 (8)*
- Spine applicator set (9)*
- Atlas applicator (10)
- Trigger 10mm applicator (11)
- Ceramic applicator (12)
- D-actor 20mm "T"(13)



* 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 RSW handpieces includes the following items:

- ShockMaster RSW handpiece or RSW handpiece short (including 1 guide tube)
- ShockMaster beam applicator
- ShockMaster D-actor 20mm S Black
- ShockMaster deep impact applicator
- 2x metal projectiles
- 1 x guide Tube
- hexagon spanner 2.5 mm
- Open-end spanner
- Paper case with foam insert
- Cleaning brush, 7mm, 35cm
- O-rings

Please refer to Section 6 for information on accessories and spare parts.

2.3 Assembling the handpiece

The projectile and applicator are not installed when the device is delivered.

Assemble the handpiece as follows:

- Remove the projectile from the handpiece packaging
- Unscrew the shaft from the handpiece. Use the supplied spanner for this purpose.
- Pull the shaft out of the handpiece handle.
- Insert a new projectile in the tube and screw the shaft back to the body (use a spanner to tighten the shaft properly).
- Screw the applicator screw cap onto the handpiece until finger-tight

NOTE

Depending on the applicator, the screw cap is in one or two pieces.

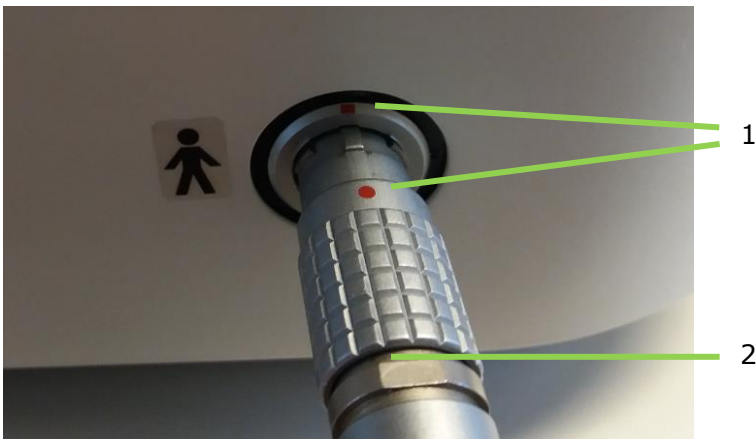
In case of two pieces, make sure that the two cap parts are screwed firmly in place before every treatment.

2.4 Handpiece connection

NOTE

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

- Connect the plug of the ShockMaster RSW 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 RSW handpieces are suitable to connect to the ShockMaster control units.

3.2 Functional checks

Perform the following functional checks after the system has been installed and the handpiece assembled:

- Check the handpiece for possible damage.
- Perform the start-up (see section 3.3 start-up).
- Release shocks in continuous shock mode. (See operating manual for control unit.)
- Check that the triggered pulses are correctly counted on the treatment pulse counter.

3.3 Start-up

NOTE

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

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



3.4 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 strictly necessary. 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

- Disconnect the RSW handpiece from the control unit.
- Unscrew the single applicator screw cap (beam, classic 15mm, 6 mm acupuncture, deep impact, focus lens, trigger 10mm, ceramic) or the double applicator screw cap (D-actor 20mm, D-actor 35mm, D-actor 20mm "T") from the handpiece.
- Screw the two-piece applicator screw cap apart (D-actor and D-actor).
- 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 finger-tight
- For fascia and spine actors always first screw the adaptor on the RSW handpiece Short and click the transmitter in the adaptor.

NOTE

The teflon cap of the focus lens is a consumable part.

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 penetrates either the unit or its tubing.

Regular cleaning of the system ensures perfect hygiene and operation of the ShockMaster RSW 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	Daily
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.

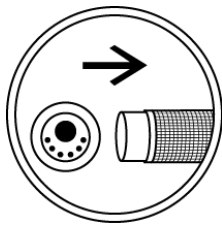
4.1.1 Cleaning the handpiece



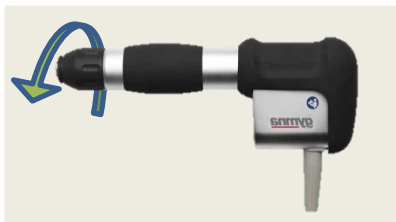
ATTENTION

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



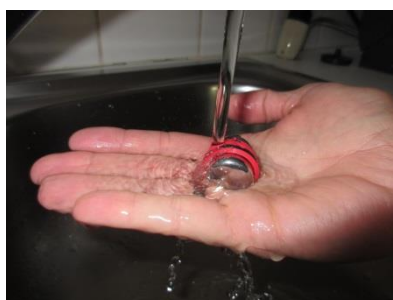
7. To clean the handpiece, the protective cushion can be pulled back and up off the handpiece handle (not needed for Handpiece Short)

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, D-actor 20mm "T" and D-actor 35mm 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 RSW handpieces revision

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



ATTENTION

The RSW handpieces should be revised about every 1,250,000 shocks. This can be done quickly and easily by the equipment user, with a revision kit that includes all required wearing parts.



ATTENTION

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

4.2.1 Contents of the ShockMaster revision kit

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

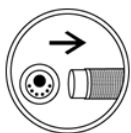
The ShockMaster Revision kit 22591 Black is available under order number 309771. The Revision kit short has order number 342705.

4.2.2 Revision of the handpiece



CAUTION

Danger of injury due to shock triggering when handpiece is open and connected.

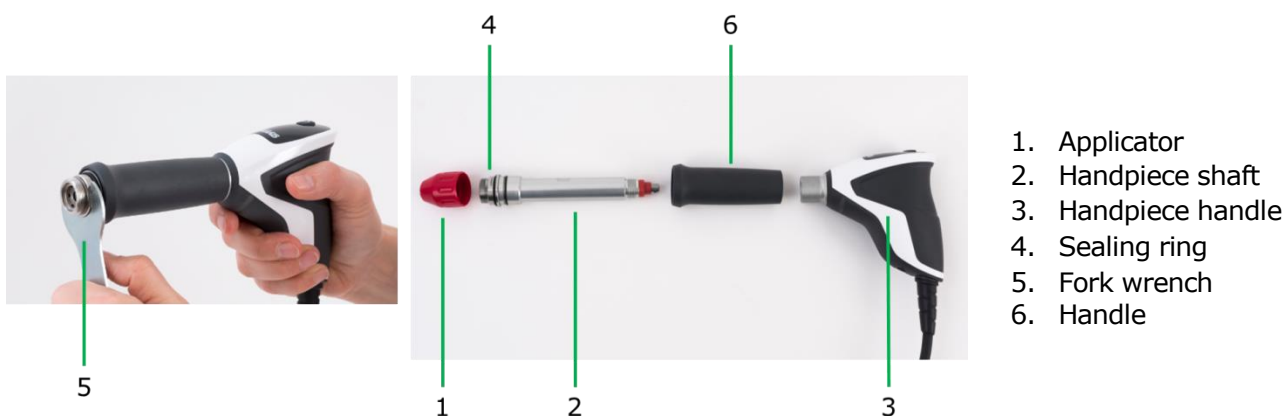


- Disconnect the handpiece from the control unit before replacing the applicator

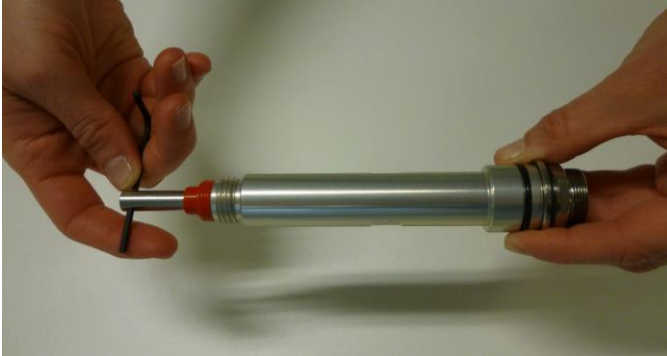
- Pull the RSW handpiece plug out of the handpiece connector of the control unit.
- Place the handpiece on a dry, clean and dust-free surface.
- Unscrew the applicator screw cap.
- Unscrew the shaft from the handpiece and pull it out of the handpiece handle. Use the supplied open-end spanner for this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

ATTENTION

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



- 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.


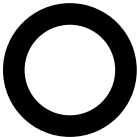
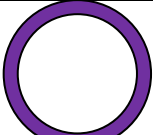

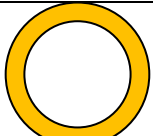

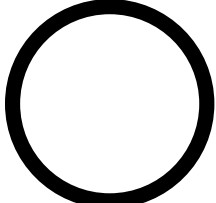
- Screw the shaft into the handpiece until finger-tight.
- Using one hand, press the handpiece firmly onto the table and tighten the shaft using the open-end spanner. It must no longer be possible to unscrew the shaft by hand.

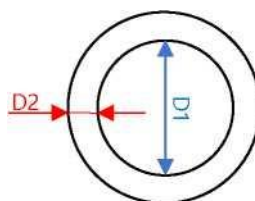


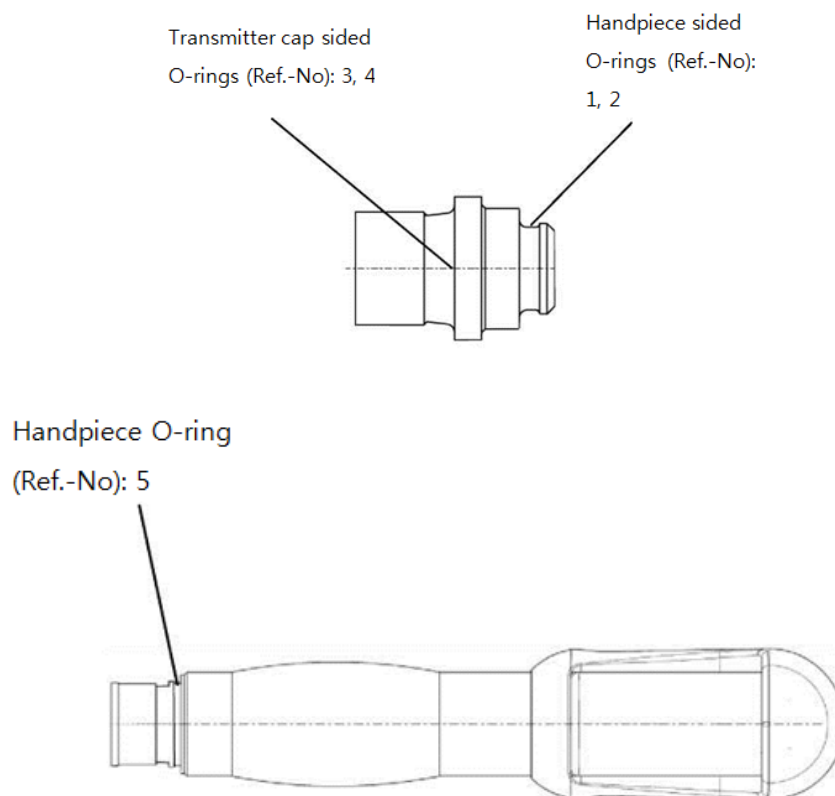
- Screw the applicator screw cap with the required applicator back onto the shaft.
- Carry out a functional check of the handpiece (see Chapter 3.2 FUNCTIONAL CHECKS).
- Reset the handpiece counter of the control unit (refer to the operating manual of your control unit).

4.2.3 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/classic Focus lens Trigger 10mm Ceramic
2		D1=12.0 mm D2=2.5mm	Deep Impact Trigger 10mm
3	 	D1=14.5 mm D2=2.5 mm	Ceramic Deep Impact
4	 	D1=13.0 mm D2=3.0 mm	Beam/classic Focus Lens
5		D1=24.0 mm D2=1.5 mm	handpiece





4.3 Maintenance

Preventive maintenance is not necessarily required.

4.4 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.

4.5 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.

4.6 Service life

The handpiece should be overhauled after around every 1.25 million shocks (see 4.3 RSW 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
Handpiece rattles when a shock is triggered – misfire	D-actor applicator screw caps are loose	Check screw caps and secure tightly

6 Accessories and spare parts

6.1 RSW handpieces

- Revision Kit 309771
- Revision Kit Short 342705
- Handpiece short body replacement set 342749

NOTE

For information on various applicators, please contact your distributor

6.2 Documentation

Accessory Manual RSW Handpiece

7 Technical specifications

7.1 RSW 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 RSW 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 RSW handpiece and applicators are a wear and tear part. We will replace new handpieces that have performed up to 2 million pulses or 2 years old (whatever occurs first) 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 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.



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