stryker

Delta Water Bath 2.0

Instructions for Use

REF # 70-76201 Delta Water Bath 2.0
REF # 70-76203 Delta Power Supply Water Bath 2.0
REF # 70-76210 Power Cord North America
REF # 70-76211 Power Cord Europe
REF # 70-76212 Power Cord UK
REF # 70-76213 Power Cord AUS/ NZL
REF # 70-76214 Power Cord Switzerland
REF # 70-76215 Power Cord Denmark
REF # 70-76216 Power Cord India
REF # 70-76217 Power Cord Brazil
REF # 70-76218 Power Cord Japan
REF # 70-76219 Power Cord China
REF # 70-76220 Power Cord Argentina

Rx Only

Table of Contents

1. How to Use this Document

1.1. About this Document

This document pertains to the Delta Water Bath 2.0 system, which consists of the following products:

- Delta Water Bath 2.0
- Power Supply
- Power Cord North America, Europe, UK, Australia/ New Zealand, Switzerland, Denmark, India, Brazil, Japan, China, Argentina

This document is the most comprehensive source of information for the safe and effective use of the product. Read this document carefully and keep for future reference. Pay special attention to safety information.

1.2. Other Applicable Documents

For additional information, see product catalogs, contact your Stryker sales representative or contact the Stryker customer service.

1.3. Disclaimer of Liability

In no instance will Stryker be responsible for incidental or consequential damages related to the product.

1.4. Definition of Conventions

The following table provides definitions of conventions used in this document.

Convention	Definition
1	Refer to graphic
▶	Instructional step that must be performed.
1.	Instructional steps that must be performed in a sequence.
•/-	Unordered list item

1.5. Definition of Terms, Abbreviations and Symbols

The following table provides definitions of terms used in this document.

Term	Definition
CAUTION (signal word)	Highlights a product reliability issue. Comply with this information to prevent product damage or malfunction.
Delta implant	Stryker plates or meshes made out of resorbable material to insert in living tissue for bone fixation.
Delta Water Bath 2.0 system	See Chapter 3.1 “*Intended Use*”.
Power cord	Connection of the power supply and the power outlet.

Term	Definition
Power supply	Provides power to the Delta Water Bath 2.0.
Drape	Single-use sterile drape made out of Polyurethane.
WARNING (signal word)	Highlights a safety-related issue. Comply with this information to prevent patient injury or hospital staff injury.

The following table provides definitions of abbreviations used in this document.

Abbreviation	Definition
CMF	Craniomaxillofacial
EEC	European Economic Community
EN	European Standard
EMC	Electromagnetic compatibility
FDA	U.S. Food and Drug Administration
HF	High Frequency
ISO	International Organization for Standardization
MRI/ MR	Magnetic Resonance Imaging/ Magnet Resonance
RF	Radio Frequency

The following table defines the symbols used in this document, on the product and on the product label.

EN ISO 7010 Graphical symbols – Safety colors and safety signs – Registered safety signs

Symbol/ number	Name: Definition
 W001	**General warning sign:** To signify a general warning.
 M002	**Refer to instruction manual/booklet:** To signify that the user instruction manual/booklet must be read.

EN ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied - Part 1 General requirements

Symbol/ number	Name: Definition
 5.1.1	**Manufacturer:** indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
 5.1.5	**Batch code:** indicates the manufacturer's batch code so that the batch or lot can be identified.
 5.1.6	**Catalog number:** indicates the manufacturer's catalog number so that the medical device can be identified.
 5.1.7	**Serial number:** Indicates the manufacturer's serial number so that the medical device can be identified.

Symbol/ number	Name: Definition
 5.2.7	**Non-Sterile:** indicates a medical device that has not been subjected to a sterilization process.
 5.2.8	**Do not use if package is damaged:** Indicates a medical device that should not be used if the package has been damaged or opened.
 5.3.7	**Temperature limit:** Indicates the temperature limits to which the medical device can be safely exposed.
 5.3.8	**Humidity limitation:** Indicates the range of humidity to which the medical device can be safely exposed.
 5.3.9	**Atmospheric pressure limit:** Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

IEC 60417 Graphical symbols for use on equipment

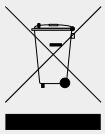
Symbol/ number	Name: Definition
 5032	**Alternating current:** To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
 5031	**Direct current:** To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals
 5010	**“ON”/“OFF” (push-push):** To indicate connection to or disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.[]Each position, “ON” or “OFF”, is a stable position.
 5041	**Caution, hot surface:** To indicate that the marked item can be hot and should not be touched without taking care.
 5140	**Non-ionizing electromagnetic radiation:** To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

Product-Specific Symbols

Symbol	Name: Definition
	**Quantity:** Indicates the number of medical devices in the packaging.
	**Note symbol:** it is used to supplement or clarify information.
GTIN	Global Trade Item Number
	**Do not sterilize:** Do not sterilize the Delta Water Bath 2.0.

Symbol	Name: Definition
50 %	Indicates the minimum filling level to reduce the heating time by 50 %.
100 %	Indicates the maximum filling level.
	*HEATING* **light is on:** Indicates that the product is heating up the water.
	*ALERT* **light is on:** Indicates either a malfunction of the product or a handling failure. For further details, see Chapter 9 "*Troubleshooting*".
	*READY* **light is on:** Indicates that the product is ready to use.

Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)

Symbol	Name: Definition
	Indicates that the product must be collected separately and must not be disposed of as unsorted municipal waste.

21 Code of Federal Regulations (CFR), section 801.109(b)(1)

Symbol	Name: Definition
Rx Only	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Regulatory marks and logos

Symbol	Definition
	CSA certified for Canada and USA
	Conformity with Annex I of Medical Device Directive 93/42/EEC.

2. Safety Information

This Chapter presents general product-related warnings, cautions and notes for the safe and effective use of the Delta Water Bath 2.0. For topic specific warnings, cautions and notes, see the corresponding Chapters.

2.1. General Information

WARNING

Risk due to use of non-original products
All products mentioned in this document are designed to function together. Combining with products from manufacturers other than Stryker may involve incalculable risks, such as increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation and/ or contamination or misalignment of the products that may lead to patient or medical staff injury.
- Combine products mentioned in this document only with corresponding Stryker products.

CAUTION

Use of damaged products
Sterile and non-sterile products may not be fully functional after multiple uses or due to misuse or due to insufficient maintenance. The use of non fully functional products may lead to product failure.
- Inspect each product before use.
- Check moving parts for free movement.
- Do not use if damage is apparent.

2.2. Product-Related Information

WARNING

Risk due to an incorrect connection to the power cord
Special treatment of an electronic product is required. Failure to comply may lead to an electric shock.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Ensure easy access to the plug of the power supply and the power cord in use by the product.
- Ensure the product is safely disconnected from the power cord when not in use or while cleaning the product.

Risk due to presence of flammable anesthetic mixtures
The product is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide. Failure to comply may lead to patient harm and product damage.
- Do not use the product in the presence of flammable anesthetic mixtures.

Risk due to modifying the product or product accessories
Modification of the product or any accessory may lead to patient harm and product damage.
- Do not modify any product or any accessory.

Risk due to using the product above an altitude of 2000 meters
Using the product above 2000 meter altitude may lead to an electronic shock.
- Only use the product under an altitude of 2000 meters.

Risk due to overfilling the Delta Water Bath 2.0
Overfilling the Delta Water Bath 2.0 may lead to water spills. Failure to comply may lead to medical staff harm.
– Do not overfill the Delta Water Bath 2.0.

CAUTION

Electromagnetic compatibility (EMC)
Portable and mobile RF communications equipment can affect the function of this product and may lead to product failure. Use of accessories, transducers and cables other than those specified or provided by Stryker of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
– Install and place the product into service according to the EMC recommendations. For further details, see Chapter 11 "*Electromagnetic Compatibility*".

Risk due to connecting a non-original Stryker power supply
Connecting to an non-original Stryker power supply may lead to product damage.
– Connect the product to the Stryker power supply only.

Risk due to using the Delta Water Bath 2.0 with a sterile drape
Using a sterile drape not made out of Polyurethane could melt while using the Delta Water Bath 2.0. Failure to comply may lead to damage of the product.
– Use only sterile Polyurethane drapes which meets at least the requirements of sterile drape stated in Chapter 10.1 "*Material Information*".

2.3. MRI Information

The Delta Water Bath 2.0 system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Delta Water Bath 2.0 system in the MR environment is unknown.

2.4. Product Notes and Surgeon Responsibilities

Multiple-use products
Instruments and storage components are multiple-use products. Use, reprocess and maintain the product as recommended in this document. For further details, see Chapter 6 "*Reprocessing*".

Surgeon responsibilities
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not provide medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

Performance of reprocessing and maintenance
Reprocessing and maintenance must be performed by trained medical staff.

3. Product Information

This Chapter presents product information of the Delta Water Bath 2.0 system.

3.1. Essential Performance

None

3.2. Intended Use

The Delta Water Bath 2.0 system is intended to heat up and keep sterile water at an operating temperature of 65 °C +/- 2 °C (149 °F +/- 35.6 °F) in order to allow to soften the Delta implant plates for contouring to the patient's specifications in the sterile area of the surgery field.

3.3. Indications for Use

The Delta Water Bath 2.0 system is not intended to come into direct or indirect contact to the patient and not to diagnose, treat, reconstruct or improve a patients condition. Therefore, the Delta Water Bath 2.0 does not have a medical indication. The Delta Water Bath 2.0 system components are delivered non sterile and are not intended to become sterilized by the user. The Delta Water Bath 2.0 shall only be used with a sterile drape that separates the non sterile from the sterile field. For further details for the sterile drape, see Chapter 10.1 "*Material Information*". Fill the Delta Water Bath 2.0 basin covered by the sterile drape with sterile water only.

3.4. Contraindications

None

3.5. Adverse Effects

None

4. Product Overview

This Chapter presents the Delta Water Bath 2.0 system. For further details about the correct use of the Delta Water Bath 2.0 system during surgery, see Chapter 5 *"Intraoperative Use"*.

4.1. Overview

Graphic 1: Delta Water Bath 2.0 system

5. Intraoperative Use

WARNING

Risk due to contact with other electrical products
Stacking or arranging the product close to other medical electrical products may lead to patient injury or to product failure. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Do not stack or arrange the product close to other electrical products.

Risk due to carrying the Delta Water Bath 2.0
Carrying the Delta Water Bath 2.0 around while filled could lead to a water spill and may lead to patient and medical staff infection due to contamination from the water.
- Lift the Delta Water Bath 2.0 by using the handles.
- Do not carry the Delta Water Bath 2.0 during surgery.

Risk due to improper pre-operative planning
Failure to inspect the Delta Water Bath 2.0 and the power supply during pre-operative planning may lead to prolonged operation time or to electrical harm if they have malfunctioned.
- Perform a functional check outside the surgery field before use.
- Do not use if damage or corrosion is apparent.
- Inspect the power supply, the power cord and the power outlet for protruding wires or insulation defects.

Risk due to incorrect positioning of the Delta Water Bath 2.0 in the surgery field
Placing the non-sterile Delta Water Bath 2.0 in the sterile area may lead to patient infection due to contamination or due to electric shock.
- Only place the Delta Water Bath 2.0 in the non-sterile area of the surgery field.
- Make sure the patient has no contact with the Delta Water Bath 2.0.

Risk due to improperly heating the implant in the Delta Water Bath 2.0
Incorrectly heating the implant in the Delta Water Bath 2.0 may lead to patient harm.
- Insert the implant into the Delta Water Bath 2.0 a maximum of 3 times for 30 seconds each. For further details, see instructions for use "*90-70005*".

Risk due to improper operation of the Delta Water Bath 2.0
Turning on the Delta Water Bath 2.0 without first filling with sterile water may lead to medical staff harm.
- Turn on the Delta Water Bath 2.0 only after filling with sterile water.
- While the Delta Water Bath 2.0 is turned on, check the water level from time to time.
- Refill if necessary to the maximum filling level, but at least to the minimum filling level.

Risk due to malfunction of the power supply during surgery
Defect or malfunction of the connection or power supply may lead to prolonged operation time.
- During surgery, have a replacement connection and power supply for the Delta Water Bath 2.0 assembly and power cord.

Handling of the product while the product is turned on
The maximum temperature of approximately 67°C (152.6°F) can be reached while the product is turned on. Allow sufficient time for cooling down after the product is turned off before handling.

5.1. Prior to Intraoperative Use

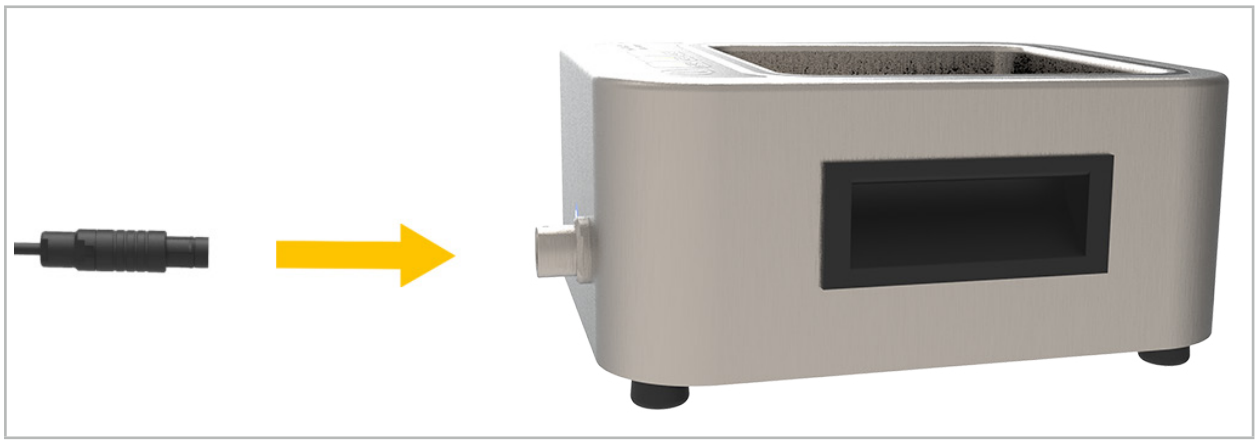
Preparation of the Delta Water Bath 2.0 system components:

1. Carefully unpack the Delta Water Bath 2.0 system components.
2. Check the Delta Water Bath 2.0 system components for damage prior to use/ surgery.

5.2. Intraoperative Use of the Delta Water Bath 2.0

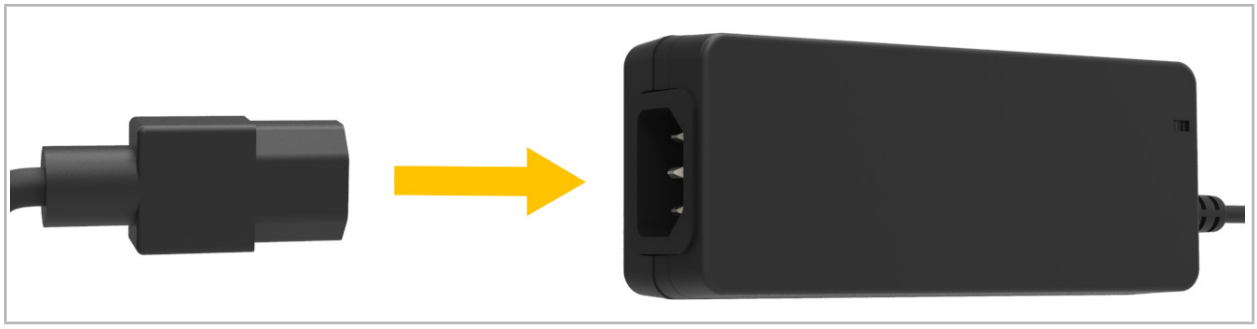
How to set up the Delta Water Bath 2.0 system:

1. Place the Delta Water Bath 2.0 on a side table of the surgery field.
   - Verify that the Delta Water Bath 2.0 is in a horizontal and stable position on the table.
2. Connect the Delta Water Bath 2.0 to the power supply. See graphic 2.



Graphic 2: Plug for the power supply

3. Connect the power supply to the power cord. See graphic 3.



Graphic 3: Connection from the power supply and the power cord

4. Plug in the power cord to the power outlet.

5. Place any provided sterile transparent Polyurethane drape over the Delta Water Bath 2.0. See graphic 4.

   - The Delta Water Bath 2.0 is fully covered by the drape.

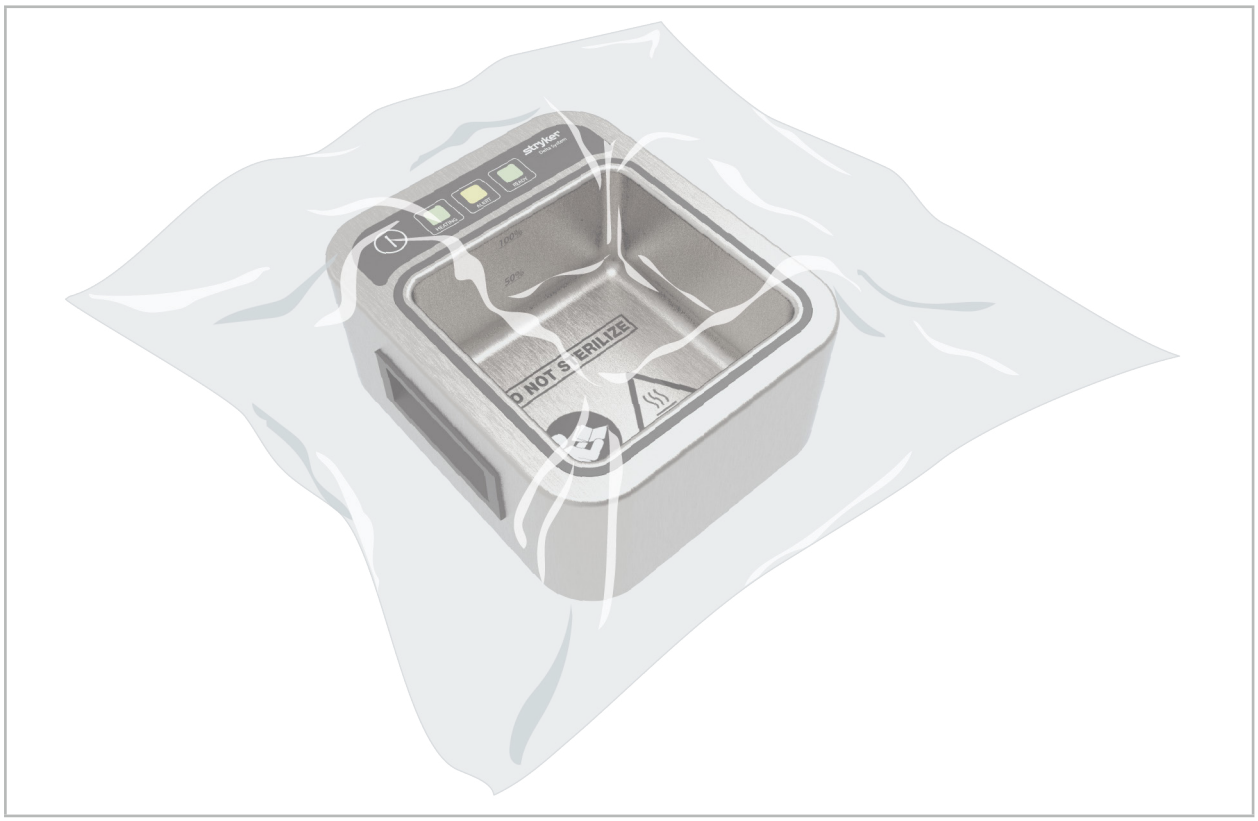
Covering the Delta Water Bath 2.0
Make sure the Delta Water Bath 2.0 is fully covered by the drape. Stryker recommends a drape with a minimum size of 80cm x 80cm (31.5in * 31.5in). For further details, see Chapter 10.1 *"Material information"*.

Graphic 4: Drape over the Delta Water Bath 2.0

6. Form the drape into the cavity of the Delta Water Bath 2.0. See graphic 5.

   - Verify that the drape fits into and stays in the Delta Water Bath 2.0.

Forming the drape into the cavity
Only accurate placement of the drape within the basin will allow proper heat transfer (and temperature regulation) of the Delta Water Bath 2.0 to the water. Pay special attention that the drape is placed flat in the cavity without crease and air enclosures, the drape shall also fit closely into the bottom edges of the basin.



Graphic 5: Drape inside the Delta Water Bath 2.0

7. Fill the Delta Water Bath 2.0 basin up to the maximum filling level with sterile water at room temperature.

   - Do not fill in pre heated water in the Delta Water Bath 2.0 system.
   - The heating time until Delta Water Bath 2.0 is ready for use will be <45 minutes.

Filling level
It will decrease the heating time down to 20 minutes by filling the Delta Water Bath 2.0 to the 50 % minimum filling level. The heating time can be further decreased by covering the Delta water bath 2.0 basin with the help of a sterile cover only.

How to use the Delta Water Bath 2.0:

1. Push the main power button to turn on the Delta Water Bath 2.0. See graphic 6.

   - The *HEATING*, the ALERT, and the READY light (see graphic 6) will illuminate for 1 second. During this time an internal system check of the Delta Water Bath 2.0 will be conducted.

Graphic 6: Main power button and *HEATING*, *ALERT* and *READY* lights

Damaged *HEATING* **and/ or** *READY* **light**
If one of the two light indicators is not illuminating or any internal failure occurs during the internal system check, the *ALERT* indicator will illuminate. When this happens the Delta Water Bath 2.0 will not heat up the water.

Damaged *ALERT* **light**
If the *ALERT* light indicator is damaged the *ALERT* indicator will not illuminate.

2. After a successful internal system check, the Delta Water Bath 2.0 will start to heat up the water.
   - The *HEATING* light will be on while the bath is heating.
   - Turn on the Delta Water Bath 2.0 for at least 45 minutes to reach the minimum temperature of 65° C (149 °F) before the procedure.
3. The Delta Water Bath 2.0 is ready for use, once the *READY* light is on.

5.3. After Intraoperative Use

How to prepare the Delta Water Bath 2.0 system components for storage after use:

1. Turn off the Delta Water Bath 2.0. See graphic 6.
   - Remove the water once the water has cooled down.
2. Remove and dispose the drape.
3. Disconnect the Delta Water Bath 2.0 from the power cord. See graphic 1 and 2.

6. Reprocessing

This Chapter presents the cleaning and disinfection procedures that were used to validate the reprocessing for the Delta Water Bath 2.0 system.

WARNING

Risk due to reprocessing an electronic product
Special treatment for reprocessing an electronic product is required. Failure to comply may lead to an electronic shock and lead to product damage.
- Do not immerse any component into water, cleaning agents, an ultrasonic washer or the automated washer.
- Ensure the Delta Water Bath 2.0 is disconnected from the power cord.
- Do not put the product into the autoclave for sterilization.
- A barrier between the non-sterile product and the sterile field in the surgery field is needed.

Non-sterile product
The product is supplied non-sterile. Do not sterilize the product.

6.1. Cleaning and Disinfection

WARNING

Risk due to not following equipment requirements
Failure to comply with the requirements of the equipment manufacturer may lead to unclean or damaged products. Unclean products may lead to patient harm.
- Follow the instructions, warnings, precautions and recommendations given by the equipment manufacturer.
- Pay special attention to cleaning/disinfection agents and equipment that are indicated for specific materials only.

Water quality
Stryker recommends to rinse the products with freshly prepared purified water/highly purified water or sterile water with less than 10cfu/ml and 0.25EU/ml to ensure sufficient cleaning.

6.1.1. Cleaning and Disinfection

Required equipment:

- Disinfectant intended for manual disinfection and compatible with applied cleaning agent and at a concentration and temperature not less than specified by the manufacturer.
- Freshly prepared purified water or sterile water
- Absorbent paper, paper wipes, soft brushes

Cleaning and disinfection procedure:

1. Prepare a paper wipe with a disinfectant solution.
   - Use a fresh paper wipe for each component.
2. Carefully wipe all surfaces of the components with the paper wipe.
   - Do not clean the inside of the connection parts.
3. Repeat step 1 to 2.
4. Visually inspect the components for remaining soil.
   - If required, repeat steps 1 to 3.
   - Pay special attention that no cleaning and disinfection solutions come into the Delta Water Bath housing from beneath/ bottom side.

7. Maintenance

The Delta Water Bath 2.0 system is not field repairable. Stryker products must be returned for maintenance or repair.

The Delta Water Bath and the power supply do not need maintenance in the field to keep basic safety and/ or to maintain electromagnetic compatibility.

Please follow country specific regulations and hospital internal service procedures to maintain effectiveness of shields and grounds.

For further details, contact your Stryker sales representative or customer service at +1 800 962 6558.

8. Transport, Storage and Disposal

This Chapter presents transport and disposal information of the Delta Water Bath 2.0 system. Also, it presents how the Delta Water Bath 2.0 system is stored in the dedicated storage components.

8.1. Transport and Storage

CAUTION

Risk due to wrong transportation of the product
Failure to properly transport the product may lead to damage of the product.
– Transport by road and air.

Risk due to incorrect storage environment
Storage of products in a humid environment for an extended period of time may cause corrosion on the product which may lead to product malfunction.
– Store all products in a dry and clean environment.

The following table provides the Stryker recommended and validated transport and storage parameters for the Delta Water Bath 2.0 system:

	Transport	Storage	Operation
Temperature	-20 to 40 °C (-4 to 104 °F)	-20 to 40 °C (-4 to 104 °F)	15 to 30 °C (59 to 86 °F)
Relative humidity	10 - 70 %	10 - 70 %	10 - 70 %
Atmospheric pressure	70 - 106 kPa	70 - 106 kPa	78.5 - 102 kPa

8.2. Disposal

For disposal of the product or the packaging follow restrictions given by legal authorities and medical facilities.

Disposal of the used water
The used water from the Delta Water Bath 2.0 is a medical waste.

9. Troubleshooting

Problem	Possible cause and solution
Delta Water Bath 2.0 has been started with less than 50 % filling level.	• Fill up the Delta Water Bath 2.0 with sterile water to at least 50 % filling level. Switch off and on the Delta Water Bath 2.0 by pushing the main power button twice.
Wrong drape is used	• For further details, see Chapter 10.1 "*Material Information*".
ALERT light is on	The Delta Water Bath 2.0 is empty: • Switch off and fill up the Delta Water Bath 2.0 with sterile water to at least 50 % filling level. Switch the Delta Water Bath 2.0 on. The drape is inserted incorrect and the heating can not take place efficiently (crease, air enclosures between the drape and the base of the Delta Water Bath 2.0): • Switch off the Delta Water Bath 2.0 and insert the drape correctly. For further details, see Chapter 5.2 "*Intraoperative Use of the Delta Water Bath 2.0*". Fill up the Delta Water Bath 2.0 with sterile water to at least 50 % filling level. Switch the Delta Water Bath 2.0 on. An unexpected system state has occurred (internal or external): • Stryker recommends to restart the Delta Water Bath 2.0 by pushing the main power button. See graphic 2. • Verify that no electromagnetic disturbance is apparent. For further details, see Chapter 11 "*Electromagnetic Compatibility*". • Return for troubleshooting or send the non-functioning components back to Stryker for a replacement (see note).
READY light is on, but the implant is not malleable	An unexpected system state has occurred: • Check the water temperature. • Restart the Delta Water Bath 2.0 system by pushing the main power button twice. • If the Delta Water Bath 2.0 system is not properly working any longer return for troubleshooting or send the non-functioning components back to Stryker for a replacement (see note).
No lights are illuminated even after turning on the Delta Water Bath 2.0 by pushing the main power button	The power supply is defective: • Check if the light on the on the Delta power supply is on. If the power supply is not working, replace the power supply and send the non-functioning power supply back to Stryker for a replacement (see note). The power supply is loose or not connected: • Check the connection between: - the Delta Water Bath 2.0 and the power supply - the power supply and the power cord - the power cord and the power outlet
Housing is deformed	An excessive mechanical impact to the housing occurs: • For further details, see Chapter 5.1 "*Prior to Intraoperative Use*". If malfunction occurs return for troubleshooting or send the non-functioning components back to Stryker for a replacement (see note).
Housing is corroded	Exposure to saline and/ or the use of an aggressive cleaning/ disinfection agent: • Send the non-functioning components back to Stryker for a replacement.

Return of the non-functioning components
If the connections are secure, there is likely a component malfunction. If available, test the Delta Water Bath 2.0 with other Stryker Delta Water Bath 2.0 components. Send the non-functioning components back to Stryker for replacement. For further details, see Chapter 12 "*Warranty, Service and Returns*".

10.1. Material Information

The following table provides the material information for the Delta Water Bath 2.0 system:

Delta Water Bath 2.0	Housing: Stainless steel
Power Supply	Housing: PC Cable: PVC
Power cable and Insulation	PVC
Sterile drape	Polyurethane Size: minimum 80cm x 80cm (31.5in x 31.5in) The drape shall withstand a temperature during use of at least 150°C (302°F). The use of the Delta Water Bath 2.0 has been validated with the Fluid Warmer Drape # 40-SD300 manufactured by Advance Medical Designs.

10.2. Technical Specifications

The following table provides the technical specifications for the Delta Water Bath 2.0 system:

Model	REF # 70-76201 Delta Water Bath 2.0
Size	Length: 210 mm Width: 175 mm Height: 90 mm
Weight	3 kg
Temperature of the water in the Delta Water Bath 2.0	65°C +/- 2°C (149°F +/- 3.6°F)
Enclosure protection	IPX0
Approvals	CSA International cCSAus-sign EN / IEC 60601-1 (3.1rd edition) EN / IEC 60601-1-2 (4th edition) ANSI/AAMI ES60601-1 CAN/CSA-C22.2 No. 60601-1 ANSI/ AAMI/ IEC 62366:2015

The following table provides the technical specifications for Delta Power Supply:

Model	REF # 70-76203 Delta Power Supply
Size	Length: 175 mm Width: 72 mm Height: 35 mm Cable length: 1150 mm
Weight	0,7 kg

Input	100-240V ~ 50-60Hz/ 2.0 - 1.0 A
Output	24V DC/ 6.67A
IP protection	IPX0
Protection class	I

The following table provides the technical specifications for Power Cord:

Model	REF # 70-76210 Power Cord North America REF # 70-76211 Power Cord Europe REF # 70-76212 Power Cord UK REF # 70-76213 Power Cord AUS/ NZL REF # 70-76214 Power Cord Switzerland REF # 70-76215 Power Cord Denmark REF # 70-76216 Power Cord India REF # 70-76217 Power Cord Brazil REF # 70-76218 Power Cord Japan REF # 70-76219 Power Cord China REF # 70-76220 Power Cord Argentina
Length	REF # 70-76210 = 3000 mm REF # 70-76211 = 2500 mm REF # 70-76212 = 2500 mm REF # 70-76213 = 2500 mm REF # 70-76214 = 2500 mm REF # 70-76215 = 2500 mm REF # 70-76216 = 2500 mm REF # 70-76217 = 2500 mm REF # 70-76218 = 2500 mm REF # 70-76219 = 2500 mm REF # 70-76220 = 2500 mm

11. Electromagnetic Compatibility

The EMC specifications apply to every product of the Delta Water Bath 2.0 system.

The Delta Water Bath 2.0 system is tested in "*Home Healthcare Environment*", more severe than the "*professional healthcare facility environment*". It can be connected to public mains networks due to its higher immunity test level.

Equipment can be used in the surgery field of a hospital except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

11.1. Compliance for each Emissions and Immunity standard

The Delta Water Bath 2.0 system fulfills the requirements of IEC 60601-1-2: 2014 with the immunity test levels for "*Home Healthcare Environment*" and emission limits of CISPR 11 Class B. The customer or the user of the Delta Water Bath 2.0 system should assure that it is used in the below specified environment.

Guidance and manufacturer's declaration

Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

11.2. Recommended separation

The Delta Water Bath 2.0 system is intended for use in an electromagnetic environment in which RF interference is controlled. The customer or user of the Delta Water Bath 2.0 system can help prevent electromagnetic interference by observing the minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the Delta Water Bath 2.0 system as recommended below. This will depend on the maximum power output of the communication device.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Delta Water Bath 2.0 system, including cables specified by Stryker. Otherwise, degradation of the performance of this equipment could result.

The Delta Water Bath 2.0 system is not suitable for use next to HF surgical equipment.

12. Warranty, Service and Returns

Stryker Craniomaxillofacial warrants this product against defects in both materials and workmanship to the registered owner at the time of purchase. All components are covered by the warranty for a period of one year from the date of purchase.

This warranty does not apply to any product which has been subject to misuse, neglect, improper installation or that which has been altered, adjusted, or tampered with by any person other than Stryker Craniomaxillofacial authorized personnel.

If upon examination by authorized service personnel, it is determined that the malfunction is due to misuse or abuse, warranty provisions will not apply. An estimate of the cost of repair work will be given to the customer prior to servicing and repairing the product.

The customer is responsible for returning the defective equipment to the factory at his or her own expense. If labeled as sterile, clean and sterilize all potentially contaminated products before returning. If contain a battery, remove battery before returning. Stryker Craniomaxillofacial does not accept or process potentially contaminated products which do not meet these requirements.

Stryker Craniomaxillofacial or its representative will service the product, repair or replace any defective parts thereof, and return the product.

If, upon examination, it is determined that the malfunction has been caused by misuse or abnormal conditions of operation, the repairs will be billed to the customer as out-of-warranty repairs. Credit cannot be issued for returns of discontinued, special, or modified items. A 20 % restocking fee will be assessed on items returned beyond 30 days after original invoice date. No credit will be issued for products being returned beyond 90 days after the original invoice date. Sterile packaged items cannot be returned for credit

The warranty as set forth herein is exclusive and in lieu of all other warranties, remedies, obligations and liabilities of Stryker Craniomaxillofacial, expressed or implied, including the implied warranties of merchantability and fitness for use for a particular purpose. Stryker expressly disclaims any and all incidental and consequential damages. These products are being sold only for the purpose described herein, and such warranty only runs to the purchaser. In no event shall Stryker Craniomaxillofacial be liable for any breach of warranty in any amount exceeding the purchase price of the product.

No agent, employee or representative of Stryker Craniomaxillofacial has the authority to bind the company to any other warranty, affirmation, or representation concerning this product.

This warranty is valid only to the original purchaser of Stryker Craniomaxillofacial products directly from Stryker Craniomaxillofacial or from a Stryker Craniomaxillofacial authorized agent. The warranty cannot be transferred or assigned by the original purchaser.

stryker

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