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## **IMPORTANT INFORMATION**

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# **ON THE SYNTHES WATER BATH SYSTEM**

### **DESCRIPTION**

The Synthes Water Bath System heats a tray of sterile water, which can be used to heat the Synthes Resorbable plates and meshes in the Operating Room sterile environment. It consists of the following components:

Water Bath Heater (cannot be sterilized)

Sterility Cover for Water Bath (sterilize using steam autoclave)

Water Bath Tray (sterilize using steam autoclave)

The Water Bath Heater is a Class I, grounded electrical device. The device is classified as ordinary equipment with respect to the ingress of water (IXPO). It is designed for use in a nonflammable anesthetic environment and for continuous operation. There are no known EMI concerns associated with the operation of this system. The Water Bath Heater cannot be sterilized, but can be used in a sterile environment when outfitted with the Sterility Cover and Water Bath Tray.

### **OPERATING INSTRUCTIONS**

Place the Water Bath Heater on an instrument table and connect the power cord to an appropriate main power supply. Place the autoclaved Sterility Cover over the device and the autoclaved Water Bath Tray into the well. Fill the Tray with sterile water or saline solution to the "Fill Line." Switch the Water Bath Heater on. When the "Ready" light illuminates after 18 minutes, the system is ready for use. The display will indicate the approximate water bath temperature during operation. Allow the system to cool before removing the Water Bath Tray and Sterility Cover.

If the display flashes "SSSS" or "HHHH", there is an internal problem with the unit. Switch the unit off, disconnect from the main power source and contact Synthes for repairs.

**WARNING:** Do not pour water directly in the well of the Water Bath Heater. Use of the Water Bath Tray is required.

### **METHOD OF USE**

After the Water Bath Heater has reached its operating temperature and the "Ready" indicator has illuminated, a plate or mesh can be placed into the water. After approximately 10 seconds, the plate or mesh can be contoured by hand. Hold the implant in the desired form until the material cools and becomes rigid. The appropriate bending template can also be used to obtain the required shape.

**CAUTION:** The resorbable screws are NOT to be heated by any means.

**WARNING:** Care must be taken when handling plates in the hot water. Use of forceps or similar instrument is recommended.

### **REPAIR**

The Water Bath Heater has no user-serviceable parts. If a problem arises with the system components, contact the Synthes Product Repairs Department at (800) 288-6698 or (719) 481-2219.

#### **Return Address:**

Repair Department, SYNTHES Maxillofacial,  
1051 Synthes Avenue, Monument, CO 80132

## EXPLANATION OF SYMBOLS AND MARKINGS



Reference Important Operating and Maintenance (Servicing) Instructions that are included with the product.



Meets standards UL 2601-1, CAN/CAS C22.2 No.601.1 for the United States and Canada. Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1.

### HOT SURFACE

This surface is hot when the unit is operating. It can remain hot even when the unit has been switched to the standby mode or detached from the power source. Do not touch this surface until it has cooled completely.

## CLEANING THE WATER BATH SYSTEM

The Water Bath Heater can be wiped clean with soap and water solution. Solvents and aggressive chemicals should not be used to clean the unit. Disconnect the unit from the main power source before cleaning. DO NOT IMMERSER OR STERILIZE THE WATER BATH HEATER.

The Water Bath Tray and Sterility Cover can be cleaned with a detergent with moderate alkalinity. Do not use abrasive cleaners or cleaning devices. Do not use solvents or aggressive chemicals.

## STERILIZATION OF THE WATER BATH TRAY AND STERILITY COVER

Method	Cycle	Temperature	Exposure Time
Steam	Gravity Displacement (Wrapped)	132°–135°C (270°–275°F)	15 Minutes
Steam	Pre-vacuum (Wrapped)	132°–135°C (270°–275°F)	8 Minutes

### CAUTION: DO NOT STERILIZE THE WATER BATH HEATER

*These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

## TECHNICAL DATA (WATER BATH HEATER)

Input:	120 VAC 50/60 HZ 2.7A
Water temperature setpoint:	70°C
Operation conditions:	18-30°C, 20-85% relative humidity, non-condensing
Storage conditions:	(-20°C) to 65°C
Weight:	3.35 kg

### CAUTION:

**FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

*Manufactured or Distributed by:*

**Synthes USA, LLC**  
1101 Synthes Avenue  
Monument, CO 80132

**Synthes GmbH**  
Luzernstrasse 21  
4528 Zuchwil, Switzerland  
+41 32 720 40 60

Note: For recognized manufacturer, refer to the product label.