Zimmer® UNIVERSAL Power System

Instruction Manual

Pneumatic

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INTENDED USE

The Zimmer® UNIVERSAL Power System is a power tool intended to be used for large and small bone surgeries (such as knee, hip, foot, hand, and shoulder).

The *Zimmer*® UNIVERSAL Power System is to be used by surgeons in the operating room environment. The population of patients is determined by the nature of the surgery and it is the responsibility of the surgeon to treat the patients according to the common practice.

The *Zimmer*® UNIVERSAL Power System can run on either battery power, electric power (when utilizing the appropriate power cord), or pneumatic power. Handpieces are designed with single or double triggers, which enable the forward and reverse functions.

All *Zimmer*® UNIVERSAL Power System attachments for drilling, sawing and reaming are designed to be connected to *Zimmer*® UNIVERSAL handpieces.

DESCRIPTION AND TECHNICAL DATA

The *Zimmer*® UNIVERSAL Power System handpiece delivers kinetic energy to cutting tools, under the form of rotation, oscillation or translation.The *Zimmer*® UNIVERSAL pneumatic handpiece is designed to operate using the appropriate high flow pneumatic hose and connection as required by the operator's facility.

PNEUMATIC HANDPIECE AND CORRESPONDING HOSES

HANDPIECE

REF 89-8507-405-00

UNIVERSAL modular pneumatic double trigger handpiece

HOSES AND ADAPTERS

REF 89-8510-456-30
89-8510-456-50
89-8510-563-00
89-8510-563-01
89-8510-565-00
89-8510-565-01
89-8510-115-60
89-8510-115-81

UNIVERSAL high flow pneumatic hose

- The UNIVERSAL modular pneumatic double trigger handpiece is used with UNIVERSAL high flow pneumatic hose (3 m or 5 m)
- Modular design offering drilling, sawing, and reaming
- Double trigger
- Progressive trigger mechanism
- Forward and reverse function
- Safety locking position
- Autoclavable high tech compound housing
- High performance motor

Technical data

Power	250 Watts (0.3 horsepower) typical
Weight	650 grams (without adapter)
Dimensions	100 mm x 208 mm x 58 mm
Speed adjustment	0 to 12'000 rpm approximately
Cannulation channel diameter	5 mm
Power source	Air or nitrogen
Normal operating pressure (in hose at handpiece)	6 to 8 bars (87 to 116 PSI)
Normal operating pressure (outside hose and handpiece)	Atmospheric pressure
Air consumption	700 L/min. approximately
Operation mode	Intermittent: 1 min on / 5 min off; 5 times with a 2 hour rest

Environmental conditions during operation

Ambient temperature	10°C to 38°C (50°F to 100°F)
Relative humidity	30% to 60%
Altitude	≤2,000 m – Not intended for high altitude environments

NOTE: There are no special requirements for transport or storage. Transport or store in an environment that limits exposure to dust, moisture and temperature extremes.

Maximum speed and power are obtained in the normal operating mode forward (clockwise rotation). Reverse (left rotation) should be used for unscrewing procedures only.

The power delivered by the UNIVERSAL modular pneumatic double trigger handpiece is dependent upon the pressure of the supplied air or nitrogen. If multiple devices are connected to one source the remaining pressure may not be sufficient to operate the system. Therefore, ensure that the pressure supplied to the device during operation is within the specified range of 6 to 8 bars.

During operation the handpiece cools down due to the airflow going through the device. This is part of normal operation.

CAUTIONS:
- Use only with *Zimmer*® UNIVERSAL attachments
- Do not immerse handpiece.

OPERATING PROCEDURE

CAUTION: Prior to initial usage, the *Zimmer*® UNIVERSAL Power System must be cleaned and sterilized per the instructions (See Cleaning, Decontamination and Sterilization Instructions).

TO CONNECT AND DISCONNECT THE ATTACHMENTS

Assemble until "click" is heard | Assembled | Disconnect pressing both buttons simultaneously

TO CONNECT THE FLEXIBLE HOSE

Position hose | Slide hose in handpiece | Turn hose right until it snaps in handpiece

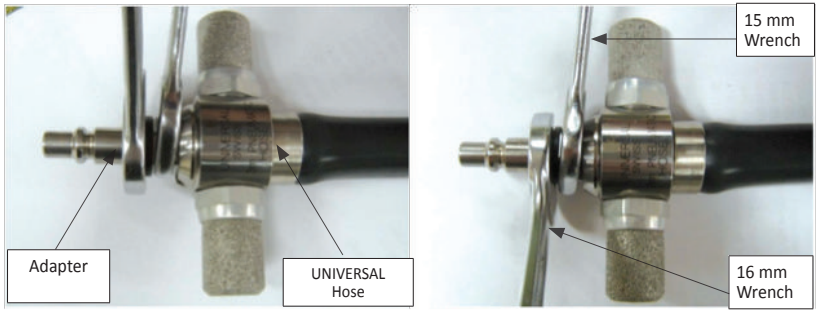
TO DISCONNECT THE FLEXIBLE HOSE

Turn hose left | Disconnect hose | Slide house out

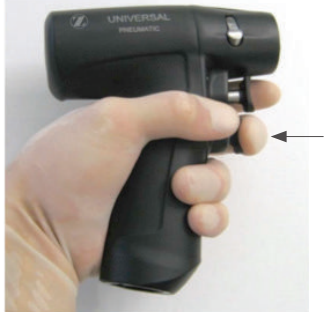
HOSE FITTING

When a hospital specific outlet is used (Synthes, Staubli, etc.) the UNIVERSAL hose must be assembled to the corresponding adapter (REF 89-8510-115-60 or 89-8510-115-81) using two wrenches to avoid twisting of the hose. Use a wrench of 15 mm on the hose and a 16 mm for the outlet side. The O-Ring for pneumatic hose (REF 89-8510-351-04) must be placed between the hose and the adapter to avoid air leakage.

CAUTION: Do not twist the hose; keep the 15 mm wrench in place while tightening. Always place the dedicated o-ring between the adapter and the hose.



TO START THE MOTOR FORWARD AND REVERSE



Forward – Lower Trigger

Reverse – Both triggers simultaneously

NOTE : Pressing higher trigger alone will not result in any operation of the handpiece.

Switch to lock or release the pneumatic motor

O: Safety position - off

1: On

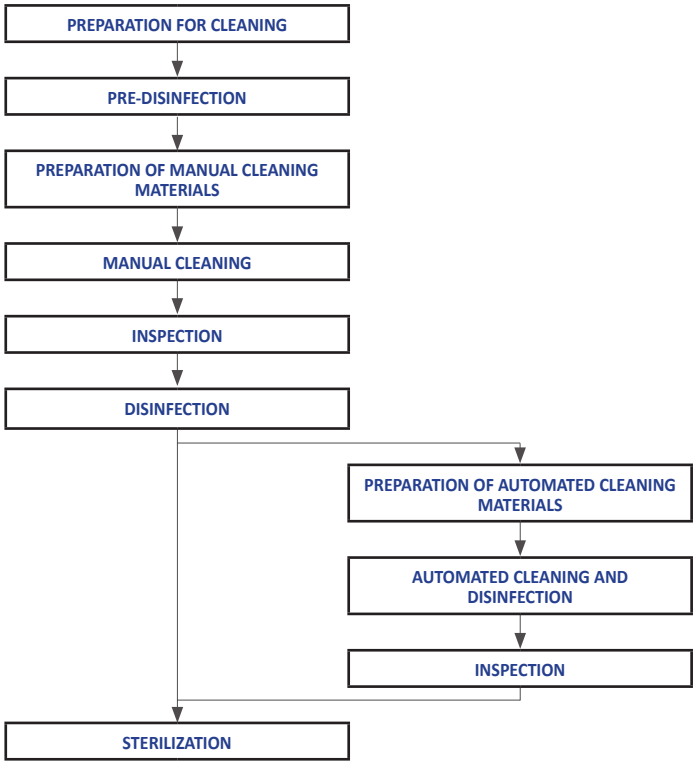
CLEANING, DECONTAMINATION AND STERILIZATION

These instructions cover the entire *Zimmer*® UNIVERSAL Power System and its accessories.

The electric power supply (REF89-8510-420-10), the battery (REF 89-8510-440-20) for Aseptic Transfer Kit (ATK) and the compact battery charger (REF 89-8510-421-00) do not required to be sterilized. From that, they are not designed to withstand any sterilization process.

These instructions need to be performed by professional staff appropriately trained in cleaning and disinfection methods.

PROCESS FLOW CHART



WARNINGS AND PRECAUTIONS

The devices must be cleaned as soon as possible after use.

WARNING: The following components must not be cleaned in an automated washer or sterilized.
For these units, the exterior may be cleaned with a cloth that has been dampened (not dripping) with a mild detergent (pH-value should be less than 9):

Zimmer® UNIVERSAL electric power supply (REF 89-8510-420-10)
Zimmer® UNIVERSAL battery (REF 89-8510-440-20) for Aseptic Transfer Kit (ATK)
Zimmer® UNIVERSAL compact battery charger (REF 89-8510-421-00)

The *Zimmer*® UNIVERSAL sterilizable battery (REF 89-8510-440-50) must not be cleaned and disinfected in an automated washer.

When using the *Zimmer*® UNIVERSAL complete Aseptic Transfer Kit (ATK) with battery, the ATK housing (REF 89-8510-440-10) and the funnel for ATK (REF 89-8510-440-30) must be cleaned, disinfected and sterilized.

Cleaners with pH 7 to 9 are recommended. The use of cleaners with higher pH-value may cause dissolution of the surface of aluminum and its alloys, plastics or compound materials. Additionally, at pH-values higher than 11, the surfaces of

stainless steel can be affected.

For cleaning and decontamination, use only detergents compatible with anodized aluminum surfaces.

PREPARATION FOR CLEANING

1. Place the handpiece in the **"safe - off"** position.
2. Disconnect air hoses, power cords or remove the batteries as instructed in Operating Procedure section of the handpiece manual.
3. Remove single use cutting consumables as instructed in Attachments manual and dispose in an appropriate container.
4. Remove all attachments as instructed in Operating Procedure section of the handpiece manual.
5. If using the ATK battery housing, open lid and remove battery from housing as instructed in Operating Procedure section of the battery/electric handpiece manual.

PRE-DISINFECTION

Immediately after use, carefully rinse the device with Reverse Osmosis (RO) or distilled water in order to remove all visible soil.

Remove any visible soil with a non-shedding soft cloth saturated with detergent (per hospital protocol).

Discard the soft cloth after use.

If the cleaning action cannot be done immediately, put the disconnected devices in a new soft cloth heavily saturated with a detergent (per hospital protocol).

PREPARATION OF MANUAL CLEANING MATERIALS

The manual cleaning process has been validated according to AAMI TIR Number 12 and ISO 17664 guidelines.

Materials:

Do not utilize detergents with phenol, aldehyde and non alkaline type (pH-value should be less than 9) active principles: quaternary ammonium and guanidine derivatives (process validated with STERIS Prolystica 2X).

Dilution and temperature parameters must follow the detergent manufacturer's specification.

Utilize RO or distilled water (hardness lower than 120 mg/L of $CaCO_3$).

Utilize non-abrasive brushes and non-abrasive, non-shedding soft cloth.

CAUTION: *Zimmer*® UNIVERSAL Power System should not be immersed or cleaned in an ultrasonic machine.

MANUAL CLEANING

Rinse the handpieces, attachements, sterilizable battery and ATK housing with RO or distilled water until all visible body fluids and tissues have been removed.

Carefully clean each part of the device with a brush and/or a soft cloth with an appropriate detergent for a minimum of 2 minutes.

While cleaning, pay particular attention to critical sites: exposed parts, narrow cavities, small openings and moving parts.

Let the detergent flow into the cavities and areas that are difficult to reach.

Rinse carefully with RO or distilled water in order to remove all detergent.

Dry the device utilizing a dry non-shedding cloth. Medical quality filtered air may be utilized if available.

INSPECTION

Inspect all devices carefully to ensure all visible soil and detergent is removed.
If necessary, repeat the steps for manual cleaning.

NOTE: If the devices are not disinfected immediately after rinsing, carefully dry the devices with a soft cloth to avoid any microbial contamination due to humidity.

DISINFECTION

Place and cover the device in a soft cloth heavily saturated with the recommended pH-value detergent/disinfectant for 30 minutes.

After the 30 minute contact time, wipe the device down with the saturated cloth, paying particular attention to joints, mated areas, crevices, and small openings.

Rinse all parts of the device with RO or distilled water.

Carefully dry the device with a non-shedding soft cloth or air.

Validated manual cleaning and disinfection procedure

	STEP	STEP DESCRIPTION	STEP INSTRUCTION	ACCESSORIES	DURATION
Cleaning Steps	1	**Contamination Removal**	Rinse product with RO or distilled water removing any visible organic material. Apply detergent with a non-shedding cloth and as necessary, with assistance of a soft bristle to brush any visible soil.	– Cold/Room temperature RO or distilled water – Soft bristle brush – Non-shedding cloth – Recommended pH-value detergent/ disinfectant	Until all visible soil is removed. **Minimum of two (2) minutes is recommended.**
	2	**Rinse**	Rinse product with RO or distilled water.	– Cold/Room temperature RO or distilled water	Until all visible detergent is removed.
	3	**Drying**	Dry the device utilizing a dry non-shedding cloth. Medical quality filtered air may be utilized if available.	– Non-shedding cloth – Medical quality filtered compressed air	Until product is visually dry.
Disinfection Steps	4	**Disinfection Application**	Apply the recommended pH-value detergent/ disinfectant to a non-shedding cloth. Cover the device's surface area with the saturated cloth.	– Recommended pH-value detergent/ disinfectant – Non-shedding cloth. – Spray bottle or other manual applicator	**Minimum of thirty (30) minutes is recommended.**
	5	**Manual Disinfection**	After 30 minutes contact time, wipe the device contact surfaces, joints and mated areas utilizing the cover cloth.	– Recommended pH-value detergent/ disinfectant – Non-shedding cloth	Manual disinfection is complete when the device's surface, joints and crevices have been manually wiped.
	6	**Final Rinse**	Rinse product under room temperature RO or distilled water.	– Room temperature RO or distilled water	**Minimum of 30 seconds.**
	7	**Final Drying**	Dry the device utilizing a dry non-shedding cloth. Medical quality filtered air may be utilized if available.	– Non shedding cloth – Medical quality filtered compressed air	Until product is visually dry.

WARNING: *Zimmer*® UNIVERSAL Power System should not be immersed or submerged in water or cleaner.

PREPARATION OF AUTOMATED CLEANING MATERIALS

The automated cleaning and disinfection process has been validated according to AAMI TIR Number 30 and ISO 17664 guidelines.

CAUTION: The manual cleaning and disinfection procedure must be performed prior to the automated cleaning and disinfection procedure.

Materials:

Detergent with neutral pH or lightly alkaline: pH < 9

Neutralizing agent

Rinse aid

Automated washer

The UNIVERSAL lift out tray (REF 89-8510-459-48) and the UNIVERSAL sterilization case (REF 89-8510-459-47) are also sold as a kit (REF 89-8510-459-46). The use of the lift out tray (REF 89-8510-459-48) has been validated and is recommended for the automated cleaning and disinfection procedure following the manual cleaning and disinfection procedure.

If the lift out tray (REF 89-8510-459-48) is not being used, load the equipment into the automated washer in a wire basket. Make sure to orient the equipment vertically to assist in drainage. Load the equipment carefully to prevent movement that may inhibit proper cleaning and always avoid contact between multiple components.

The components should be positioned on the lift out tray following the diagrams printed on the lift out tray. Do not overload the lift out tray.

AUTOMATED CLEANING AND DISINFECTION

Put medical devices in the automated washer. Avoid all contact between the devices (movement may damage devices and may jeopardize the cleaning operation).

Put implements so that holes are aimed downwards to allow proper water drainage.

Start the automated washer.

Automated cleaning and disinfection procedure

STEP DESCRIPTION	STEP INSTRUCTION	ACCESSORIES	DURATION
Automated washer	Place entire device into the automated washer, placing implements so that holes are aligned downward.	– Automated washer – Disassembled device – Washer cleaning solution – Washer neutralizing solution	Minimum total cycle time: 51 minutes when including all steps below.

Validated automated washer cycle

Step	Minimum time	Recommended temperature
Pre-Wash	2:00 minutes	Water temperature 20°C (68°F)
Cleaning	5:00 minutes	Water temperature 55°C (131°F)
Neutralizing	2:00 minutes	Water temperature 20°C (68°F)
Rinse I	2:00 minutes	Water temperature 20°C (68°F)
Rinse II (Final)	5:00 minutes	Water temperature 93°C (200°F)
Drying	35:00 minutes	Chamber temperature 99°C (210°F)

Only washing parameters shown above have been validated for cleaning effectiveness.

However, the performance of *Zimmer*® UNIVERSAL Power System is not affected in case lower temperature and/or shorter dwell time are used.

INSPECTION

Inspect each part of the devices to make sure all soil is removed.
If necessary, repeat the cleaning process.

STERILIZATION

The referenced steam sterilization cycle parameters listed below have been validated and provide a sterile result by steam sterilization according to ANSI/AAMI/ISO 17665-1:2006, Sterilization of Health Care Products. Part 1: Moist Heat. The steam sterilization process for these products has been validated to provide a sterility assurance level (SAL) of 10-6 or better when using the sterilization cases (REF 89-8510-459-41 or REF 89-8510-459-42 or REF 89-8510-459-43 or REF 89-8510-459-45 or REF 89-8510-459-46). Use of these UNIVERSAL sterilization cases is strongly recommended.

Please note that the processes described in this chapter are the only ones covered by our warranty conditions. Any other sterilization processes must not be used, with the risk to induce a premature wear and a deterioration of the device.

The steam sterilization procedure must be carried out in a qualified autoclave.

The components should be positioned in the cases following the diagrams printed on the cases. Do not overload the cases.

CAUTIONS:
- **For pneumatic handpiece:** Remove all washing caps (REF 89-8510-455-50, REF 89-8510-555-00) on hoses and on handpiece air inlet before the sterilization process.
- Do not subject any cap to the sterilization process.

WARNINGS:
- The *Zimmer*® UNIVERSAL sterilizable battery (REF 89-8510-440-50) must be sterilized with flash autoclave cycle. **Do not exceed 4 minutes at 132°C (270°F) or 3 minutes at 134°C (273°F).**
- The *Zimmer*® UNIVERSAL sterilizable battery is the only component of the *Zimmer*® UNIVERSAL Power System that can be sterilized using STERRAD® Technology. For details refer to the STERRAD® STERILITY GUIDE.
- The use of lift out tray (REF 89-8510-459-48) with another sterilization case than the recommended (REF 89-8510-459-47), must be validated prior to use.

The *Zimmer*® UNIVERSAL handpieces and accessories (except the UNIVERSAL sterilizable battery REF 89-8510-440-50) have been validated to withstand the following steam sterilization processes:

Steam sterilization cycle parameters

Steam cycle type	Temperature	Steam dwell time	Minimum dry time
Pre-Vacuum	132° C / 270° F	4 Minutes	8 Minutes
Pre-Vacuum	132° C / 270° F	8 Minutes	8 Minutes
Pre-Vacuum	134° C / 273° F	3 Minutes	8 Minutes
Pre-Vacuum	134° C / 273° F	18 Minutes	8 Minutes

WARNINGS AND PRECAUTIONS

CAUTION: Use in operation room temperature conditions only.

- Only medical professionals who are thoroughly familiar with the *Zimmer*® UNIVERSAL Power System function, application and instruction for use should operate any *Zimmer*® UNIVERSAL power equipment.
- *Zimmer*® UNIVERSAL Power System should neither be immersed nor cleaned in an ultrasonic machine.
- Do not use alkaline cleaning agents with a pH-value greater than 9.
- For cleaning and decontamination, use only detergents compatible with anodized aluminum surfaces.

- Only use an Electric/Battery or pneumatic handpiece, attachments and cutting tools in good working condition. Do not use devices if they appear to be damaged or defective.
- Cutting tools have to be discarded in sharps container after use.
- Do not use in presence of flammable products.
- Do not use accessories or hoses other than those specified or sold by Zimmer.
- This product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this product should be observed to verify normal operation.
- For intermittent (1 min on / 5 min off ; 5 times with a 2 hour rest) operation only.
- It is highly recommended to continuously moisten bones when drilling, cutting, or reaming.
- Allow sufficient time for cooling the *Zimmer*® UNIVERSAL Power System after autoclave in order to use it at a normal operating room temperature.
- The use of a *Zimmer*® UNIVERSAL sterilization case is strongly recommended.
- The use of lift out tray (REF 89-8510-459-48) with another sterilization case than the recommended (REF 89-8510-459-47), must be validated prior to use.
- The *Zimmer*® UNIVERSAL sterilizable battery (REF 89-8510-440-50) must be sterilized with flash autoclave cycle. Do not exceed 4 minutes at 132°C (270°F) or 3 minutes at 134°C (273°F).
- The manual cleaning and disinfection procedure must be performed prior to the automated cleaning and disinfection procedure. Critical sites must be manually pre cleaned with a non-abrasive brush before the automated washer cycle.
- The *Zimmer*® UNIVERSAL sterilizable battery (REF 89-8510-440-50) is the only component of the *Zimmer*® UNIVERSAL Power System that can be sterilized using STERRAD® Technology.
- Prior to initial usage, the *Zimmer*® UNIVERSAL Power System must be cleaned and sterilized per the instructions (See Cleaning, Decontamination and Sterilization Instructions).

TECHNICAL SERVICE

CAUTIONS:
- Rough shocks/handling should be avoided.
- Do not attempt to disassemble the equipment. It is a factory sealed unit with no user serviceable parts inside. No modification of the equipment is allowed.
- Zimmer is not liable for any device malfunction resulting from repairs or service not performed by a Zimmer authorized service center.
- **Always decontaminate the system before returning to Zimmer.**

SERVICE INFORMATION

The *Zimmer*® UNIVERSAL Power System should be returned every 12 months for inspection and preventive maintenance. Annual factory calibration checks are strongly recommended to verify continued accuracy.

RETURN AUTHORIZATION AND REPLACEMENT INFORMATION

When it is necessary to return the *Zimmer*® UNIVERSAL Power System for inspection, preventive maintenance or repair within the U.S.A. call 1-800-830-0970 to receive a Return Goods Authorization (RGA) number.
Outside the U.S.A., contact your local Zimmer representative.

The instrument must be properly packaged when sent in for repair. If the original packaging is no longer available, proper packaging can be requested when the RGA is received.

A purchase order must accompany all equipment for repair. The customer will be responsible for all shipping charges.

WARRANTY INFORMATION (U.S.A. ONLY)

Zimmer Surgical warrants that the *Zimmer*® UNIVERSAL Power System, along with all parts and accessories, have been tested and inspected, and have left the factory in proper working condition, free from visible defects.

Zimmer Surgical warrants to the first consumer purchaser of new *Zimmer*® UNIVERSAL Power System and accessories will, under normal and reasonable use, be free from defects in material and workmanship for one (1) year after the date of shipment from the factory. The warranty period for hoses is six (6) months. *Zimmer*® UNIVERSAL Power System consumables are warranted to be free from defects in material and workmanship upon delivery. During the warranty period, Zimmer Surgical shall repair (or at its sole option replace) the defective product or part without cost to the purchaser. Defective parts replaced under this warranty shall become the property of Zimmer Surgical. This warranty does not cover damage caused by misuse, abuse, accident, neglect, or any use not prescribed in this manual. If the unit becomes defective because of misuse or abnormal conditions of operation, repairs will be billed at our current rate.

ALL OTHER WARRANTIES, EXPRESS, IMPLIED, OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN TIME TO THE PERIOD OF THE WARRANTY GRANTED HEREBY. SOME STATES DO NOT ALLOW LIMITATIONS ON THE DURATION OF AN IMPLIED WARRANTY, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO YOU.

Neither Zimmer Surgical nor the Zimmer distributor who sells the *Zimmer*® UNIVERSAL Power System is responsible for indirect, incidental, or consequential damages. Some states do not allow the exclusion of incidental or consequential damages, so the above limitations or exclusions may not apply to you.

WARRANTY (OUTSIDE U.S.A.)

Contact your local Zimmer sales representative for warranty information.

CONTACT INFORMATION

- Inside the U.S.A., call the Zimmer Customer Service Department at 1-800-348-2759.
- Outside the U.S.A., contact your local Zimmer sales representative.

SYMBOLOGY

Graphic	What it means
	Consult instructions for use and accompanying documents.
	Caution.
	Do not immerse.
	Do not discard with household waste.
CE 0124	Conform to the European Medical Device Directive 93/42/CEE + 2007/47/CE for class IIa medical devices (notified body number)
LOT	Lot number.
SN	Serial number.
REF	Reference number or product number.
QTY	Quantity contained in package.
Rx only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Can be recycled.
	Manufactured by.
	Date of manufacture.