

STERILIZATION INSTRUCTIONS

REFER TO THE PACKAGE INSERT FOR DETAILED INSTRUCTIONS FOR USE.

Reprocessing Instructions for ExactechGPS® Trackers

To ensure the longevity and functionality of these instruments, proper handling and care is vital. Some common sterilization methods are not approved for use, so it is important to pay attention to the following recommendations:

Manual General Cleaning

Equipment: Ultrasonic cleaner, cleaning brush, enzymatic detergent (neutral pH), running water (tap, purified)

1. Pre-rinse under warm water (<math><45 +0/-5^{\circ}\text{C}</math>, $113 +0/-9^{\circ}\text{F}$) for at least two minutes to remove gross debris.
2. Completely immerse in ultrasonic cleaning bath with **neutral pH enzymatic detergent solution**, and cycle for at least 10 minutes at or below $95^{\circ}\text{F} +0/-9^{\circ}\text{F}$ (or $35^{\circ}\text{C} +0/-5^{\circ}\text{C}$).
3. Remove any remaining debris from crevices using a brush, rinse for at least two minutes under purified running water, and dry using an absorbent, non-shedding cloth until all moisture is removed.
4. Visually inspect for cleanliness and progress to sterilization.

Recommended Sterilization Methods

Equipment: STERRAD® or V-Pro® cycles are validated using the following parameters:

Sterilizer Equipment	Cycle
STERRAD® 100NX	Express
STERRAD® NX	Standard
V-Pro® Max	Non-Lumen

Note: The preferred method of sterilization is the low temperature method. Both this and the steam sterilization method have been demonstrated to be safe for patients.

Packaging Instructions

Before packaging, visually inspect for damage and wear (e.g. corrosion, discoloration and wear):

1. Instruments should be placed in a perforated tray with lid, double-wrapped using the simultaneous envelope folding technique. A polymer tray is validated, a stainless-steel equivalent is possible provided that proper air circulation is ensured.
2. They can also be placed into a double non-woven pouch conform to EN ISO 11607-1 and EN ISO 11607-2 requirements, cleared for H₂O₂ (Hydrogen Peroxide) sterilization by Health Authorities. Amcor 98ULT01240 120x400, 93g/m² non-woven polyolefin, PET/PP is validated.



IMPORTANT

Here are examples of trackers that have been cleaned and sterilized properly.