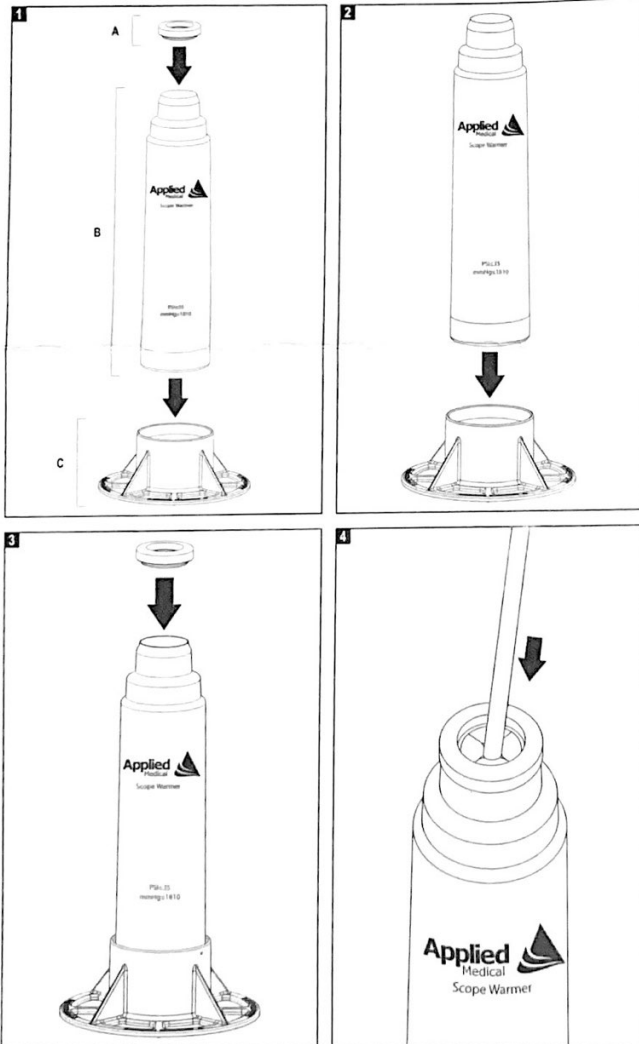
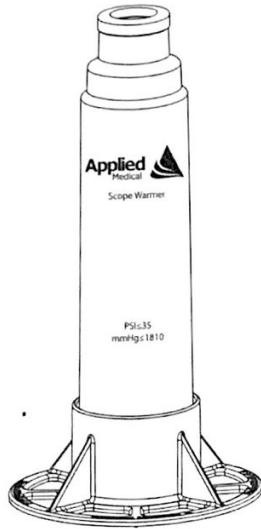


SCOPE WARMER

Instructions For Use
 Instrucciones de uso
 Mode d'emploi
 Istruzioni per l'uso
 Gebrauchsanweisung
 Instructies voor gebruik
 Bruksanvisning
 Bruksanvisning
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ENGLISH

INDICATIONS:

The Scope Warmer is indicated to rinse the lens and warm the scope to body temperature. In order to prevent laparoscope fogging during a laparoscopic procedure.

DESCRIPTION:

The Applied Medical Scope Warmer is an insulated container that consists of three components: a reusable bottle, a reusable base, and a disposable seal. The bottle holds warm sterile water used to warm a laparoscope. The base is designed to prevent inadvertent tipping of the Scope Warmer bottle when placed on a table. The seal prevents heat loss from the top of the bottle and provides easy access for the laparoscope.

KEY - ILLUSTRATION AND TERMINOLOGY (Illustration 1):

- A. Disposable Seal
- B. Reusable Bottle
- C. Reusable Base

WARNINGS:

- Do not use if the product or sterile package is damaged.
- Disposable Seals: This device was designed and tested for single patient use only. Do not reuse, reprocess or sterilize this device. Reuse, reprocessing or sterilization may alter the structural and/or functional integrity of this device which may result in patient injury, infection, illness or death. Risk of residual contamination and sterilization failure may lead to patient injury, infection, illness or death.

INSTRUCTIONS FOR USE:

- Prior to use, verify the bottle and base have been cleaned and sterilized per the instructions provided below. Inspect the Scope Warmer components visually for any damage resulting from storage or sterilization.
- Fill the bottle 2/3 to 3/4 full with sterile warm water.
- Place the bottle into the base to prevent tipping (Illustration 1).
- Position and press the disposable seal into place (Illustration 2).
- Place the laparoscope into the bottle through the slots in the seal. Leave the laparoscope in the Scope Warmer until it is ready to be used (Illustration 3).
- If the lens of the scope becomes dirty or fogged during the procedure, the laparoscope can be reinserted into the Scope Warmer, briefly rewarmed and cleaned.
- When the procedure is complete, dispose of the seal. Clean and dry the base and bottle and prepare them for sterilization according to instructions provided below.

CLEANING AND STERILIZATION:

The bottle and base are supplied NON-STERILE and must be sterilized before use. Prior to sterilization, meticulously clean and remove all adherent material from the internal and external surfaces of the bottle and base by using an enzymatic detergent and soft brushes as required. Do not use steel wool, wire brushes or highly abrasive detergent cleaners. The bottle and base should then be thoroughly rinsed with copious amounts of ambient temperature deionized water and inspected prior to sterilization. The bottle and base must be completely dried prior to sterilization. Dry the exterior surfaces with clean, lint free wipes. The interior of the bottle can be dried by inverting and allowing to air dry.

For autoclave sterilization of the bottle and base, follow these recommended steam sterilization parameters:

	Gravity	Prevacuum	Prevacuum
Temperature	132° C - *137° C (270° F - *279° F)	132° C - *137° C (270° F - *279° F)	132° C - *137° C (270° F - *279° F)
Unit configuration	Unwrapped	Unwrapped	Wrapped
Cycle time	4 minutes	3 minutes	4 minutes

* Maximum sterilization time should not exceed 30 minutes

WARNING: The Scope Warmer bottle should be positioned horizontally during sterilization processing. The Scope Warmer unit involves a vacuum bottle and exposure to unusually high sterilization temperature and high pressure may cause structural deformation.




For gas plasma sterilization The Scope Warmer unit has been validated with the STERRAD 100S sterilization system.

HOW SUPPLIED:

The bottle and base are supplied NON-STERILE and must be sterilized before use. See cleaning and sterilization. The disposable seals are supplied sterile and for single patient use.

STORAGE AND HANDLING:

Handle with care. Product should be stored in a clean, cool, dry area away from chemical fumes.

	<p>Do not use if package is damaged No utilice el producto si el envoltorio está dañado Ne pas utiliser si l'emballage est endommagé Non utilizzare se la confezione è danneggiata Nicht verwenden, wenn die Verpackung beschädigt ist Niet gebruiken indien de verpakking is beschadigd Får inte användas om förpackningen är skadad Må ikke anvendes, hvis pakningen er beskadiget Älä käyttää, jos pakkaus ei ole ehjä Skal ikke brukes hvis pakningen er skadet Não utilize se a embalagem estiver danificada</p>
	<p>CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. PRECAUCIÓN: las leyes federales de los Estados Unidos solo permiten la venta de este dispositivo por parte un médico o por prescripción facultativa. ATTENTION: la loi fédérale américaine stipule que la vente de ce dispositif est réservée aux médecins ou sur prescription médicale ATTENZIONE: la legge federale statunitense limita la vendita di questo dispositivo a medici o su prescrizione medica. VORSICHT: US-Bundesgesetz beschränkt den Verkauf dieses Produkts an einen Arzt oder auf dessen Anordnung. Let op: Krachtens de federale wetgeving van de VS mag dit hulpmiddel alleen door of in opdracht van een arts worden gekocht. FÖRSIKTIGHET: Enligt federal lag (USA) får den här produkten endast säljas av eller på ordination av läkare. FORSIGTIG: Ifølge amerikansk lovgivning må denne anordning kun sælges af eller på foranledning af en læge. VAROITUS: Liittovaltion (Yhdysvallat) lain mukaan tätä laitetta saa myydä vain lääkäri tai lääkärin määräyksestä. FØRSIKTIG: Føderal lov (USA) begrenser salg av dette utstyret til leger eller etter ordre fra leger. CUIDADO: o direito federal dos E.U.A. restringe a venda deste dispositivo por ou em nome de um médico.</p>
	<p>Not made with natural rubber latex No contiene látex de caucho natural Non fabriqué avec du latex de caoutchouc naturel Non prodotto con lattice di gomma naturale Ohne Naturkautschuk hergestellt Niet vervaardigd met natuurlijk rubberlatex Inte tillverkad med naturlig gummilátex Ikke fremstillet med naturgummilátex Ei sisällä luonnonkumilátexia Ikke laget med naturgummilátex Sem látex de borracha natural</p>

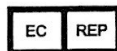
REFER TO THE ELECTRONIC SYMBOLS GLOSSARY AT WWW.APPLIEDMEDICAL.COM/SYMBOLSGLOSSARY FOR EXPLANATIONS OF SYMBOLS USED IN DEVICE LABELING.

IMPORTANT WARRANTY INFORMATION:

1. Limited Warranty. Applied warrants that Product will: (i) conform to the written specifications furnished to the Purchaser; and (ii) comply at the time of shipment with the then-applicable requirements of the U.S. Food, Drug and Cosmetic Act and regulations promulgated thereunder.
2. Warranty Claims. For any Product that does not comply with the Limited Warranty set forth above, Applied will, in its discretion: (i) repair or replace the Product at its sole expense; or (ii) refund the full purchase price of the Product. Applied's obligations under this section are subject to Purchaser's compliance with all instructions and requirements regarding the use of the Product.
3. Exclusion of Other Warranties and Remedies. Except as provided above, Applied excludes all other warranties, whether express or implied, by operation of law or otherwise, including without limitation any implied warranties of merchantability or fitness for a particular purpose. In no event shall Applied be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of any Product. Applied neither assumes, nor authorizes, any other person to assume for it, any other additional liability or responsibility in connection with the Products. IN NO EVENT SHALL APPLIED'S LIABILITY UNDER THIS LIMITED WARRANTY EXCEED THE PURCHASE PRICE OF THE PRODUCT.



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