INDICATIONS:
The Scope Warmer is indicated to reheat 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 D):
A. Disposable Seal
B. Reusable Bottle
C. Reusable Base

WARNINGS:
- Do not use the product or sterile package if damaged.
- Do not use this device for any other than the intended use.
- Do not reuse, repurpose, or reprocess this device. Evidence of processing or sterilization may alter the structural and/or functional integrity of the 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, ensure 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 base on the table to prevent tipping (Illustration D).
- Position and press the disposable seal into place (Illustration D).
- 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 D).
- If the base of the scope becomes dry 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 NOS-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 distilled 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 steam sterilization of the bottle and base, follow these recommended steam sterilization parameters:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Gravity</th>
<th>Prevacuum</th>
<th>Prevacuum</th>
</tr>
</thead>
<tbody>
<tr>
<td>132°F * * 133°C</td>
<td>5 minutes</td>
<td>3 minutes</td>
<td>4 minutes</td>
</tr>
<tr>
<td>270°F * 279°F</td>
<td>Unwrapped</td>
<td>Unwrapped</td>
<td>Wrapped</td>
</tr>
</tbody>
</table>

*Maximum sterilization time should not exceed 30 minutes.

WARNING: The Scope Warmer bottle should be positioned horizontally during sterilization processing. The Scope Warmer must be allowed to cool to room temperature and be exposed to personnel high heat 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 NOS-STERILE and must be sterilized before use. See cleaning and sterilization. All reusable components are supplied sterile for single patient use.

STORAGE AND HANDLING:
Handle with care. Product should be stored in a clean, cool, dry area away from chemical fumes.
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
För inte användas om förpackningen är skadad
Må ikke anvendes, hvis pakningen er beskadiget
Älä käytä, jos pakkaus on ollut epätasainen
Skal inte brukes hvis pakningen er skadet
Nào sử dụng khi bao bì bị hỏng

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.
Let op: Krachtsen des federale wetgeving van de VS mag dit hutmiddel 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.
FORSIGTISIG: fleige amerikansk lovgivning må denne anordning kun sælges af eller på foranledning af en læge.
VAROITUS: Lääkäron (Yhdysvallat) lain mukaan tätä laitetta saa myydä vain lääkäriin määräysten mukaan.
FORSIKTIG: Federal lov (USA) begrenser salg av dette utstyret til leger eller etter ordre fra leger.
CUIDADO: el derecho federal dos E.U.A. restringe a venda deste dispositivo por ou em nome de um médico.

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 tillverkat med naturlig gummi latex
Ikke fremstillet med naturgummilatex
Ei sisällä luonnonkummi-latexia
Ikke laget med naturgummi-latex
Sem látex de borracha natural

REx 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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