



DURAHOLDER™ INSTRUMENT PROTECTION SYSTEM INSTRUCTIONS FOR USE (IFU)

Description

The Bioseal® Duraholder™ product family uses Halyard sterilization wrap to form a series of pockets for the protection and organization of surgical instruments during the sterilization process. The Duraholder™ is intended for single use inside a sterility maintenance system and is not intended to provide a sterile barrier. The Duraholder™ will allow sterilization of the contents to occur in a steam autoclave utilizing a sterilization and drying cycle that has been validated by the user for the equipment and procedures employed at the user facility. **The Duraholder™ is intended for a single sterilization cycle use only and should be discarded after use. The Duraholder™ does NOT provide a sterile barrier and MUST be used in conjunction with a sterile barrier system to maintain sterility.**

Indications for Use

The Duraholder™ is intended to protect and organize surgical instrumentation while facilitating the sterilization process by allowing steam penetration and drying. Bioseal® has verified through laboratory testing that the Duraholder™ is suitable for use in sterilization process methods and cycles for which they have been tested. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the healthcare facility to ensure that conditions essential to sterilization can be achieved. Bioseal® does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices processed in the Duraholder™ that should have been properly cleaned and/or sterilized by the end user prior to use.

See sterilization parameters tested for wrapped, pouched and container systems below.

Warnings

- Do not use Duraholder™ if damage is found.
- Do not sterilize with dry heat or radiation.
- Single use only.

Precautions

Do not open case with a sharp knife, as it may cut the Duraholder™.

Directions for Use

Duraholder™ should be used in accordance with the recommendations of ANSI/AAMI ST79.

Storage Prior to Use

Storage location should be clean, dry, and lint-free.

Prior to Use

Cleaning/Decontamination of instruments. The health care facility is responsible for ensuring that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST35 provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair and process performance.

After cleaning, disinfecting, and drying, instruments can be placed into the Duraholder™. An appropriate process indicator can be placed inside the innermost pocket. The top flap should be folded over and the Duraholder™ can be loosely rolled up, folded over, or left flat. Next, the Bioseal® Duraholder™ IPS should be placed into a protective sterilization wrap, pouch or placed into a sterilization container system to provide a sterile barrier. **The Duraholder™ does NOT provide a sterile barrier and MUST be used in conjunction with a sterile barrier system to maintain sterility.**

Sterilization

Sterility. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved and that specific configuration of the Duraholder™, sterility barrier (sterilization wrap, pouch or container system), and the specific contents are acceptable for the sterilization process and for the requirements at the point of use.

ANSI/AAMI ST33 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities cover the selection and use of reusable rigid sterilizer container systems. Guidelines are provided by this standard for preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

Instruments sterilized in the Duraholder™ may require other sterilization parameters; Bioseal® has validated steam sterilization cycles under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters described below. Use of ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended.

*Gravity Displacement Steam Sterilizer - **Wrapped***

- Minimum 132° C, 12 minutes
- Minimum 20 minutes drying time

*Pre-Vac Steam Sterilizer (HI-VAC) – **Wrapped, Pouched or Container System***

- 4 preconditioning pulses
- Minimum 132° C, 4 minutes
- Minimum 30 minutes drying time

Since Bioseal® is not familiar with individual hospital handling procedures, we assume no responsibility for sterilization of product by a hospital even if the general above guidelines are followed.

Sterility Maintenance

Storage and Shelf Life. The Duraholder™ that has been processed and wrapped or pouched to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped instrument to prevent damage to the sterile barrier. The health care facility should establish a shelf life for the wrapped Duraholder™ based upon the recommendations of the wrap or pouch manufacturer. The user must be aware that maintenance of sterility is event related and that the probability of an occurrence of a contaminating event increases over time, with handling and the packaging method used.

Opening

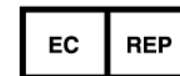
Inspect for wetness, damage or other contaminants before and after opening. If wetness, damage or contaminants are present, do not use and re-sterilize instruments with an unprocessed Duraholder™.

Disposal

Do not reuse. Duraholder™ is not intended for re-use and if reused, may not conform to performance standards. Dispose of based upon local and state regulations.



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