

Product description, sterilization and indications for use.



1shot dental x-ray holders, hold dental x-ray image recording devices, including film, phosphorplates (PSPs) and sensors, for sizes 0, 1 and 2 in the mouth and align the dental x-ray tube on 3 planes.

Multi use

1shot dental x-ray holders are provided non-sterile. Reusable holders must be cleaned and sterilised prior to use or reuse on patients. Reuse of 1shot dental x-ray holders without cleaning and sterilization may cause harm to the patient in the transfer of blood, tissue, or saliva that may contain infectious disease.

Preparation

Impurities need to be removed from the 1shot dental x-ray holders directly after use (within two hours maximum) To do so, use running water or an FDA approved and or CE Marked disinfectant solution. The disinfectant's effectiveness should be established, suitable, and compatible with 1shot dental x-ray holders.

Instruments are thoroughly cleaned and dried before being wrapped or placed in a container system.

Autoclaving

- **Temperature and Pressure:** The autoclave must reach and maintain a temperature of 121–134°C (250–273°F) under pressure.
- **Sterilization Time:**
 - Wrapped items: Typically 12–30 minutes at 121°C.
 - Unwrapped items: Typically 6–15 minutes at 121°C or 3 minutes at 134°C.
 - Some dental professionals recommend longer sterilization times for heavily soiled instruments or when using a gravity displacement autoclave.
- **Cycle:** The autoclave cycle should be selected based on the load (wrapped, unwrapped, liquids, etc.).

Recommended sterilization instructions

In USA dental settings, general autoclave sterilization typically involves high-temperature, high-pressure steam at 121–134°C (250–273°F) for 30–60 minutes, depending on the load. Other parameters like pressure and time might vary depending on the specific autoclave model and the type of load being sterilized. Please note 1shot dental holders are one piece.

Dry heat sterilization, boiling, and cleaning solutions are not recommended as sterilization methods for 1shot dental x-ray holders. Temperature and effective sterilization cannot be guaranteed.

Drying and Storage

After the sterilization cycle, the autoclave may have a drying cycle. This typically takes 25–40 minutes. Wet instruments can compromise the packaging integrity and sterility, so proper drying is crucial.

Sterilized instruments should be stored in a clean, dry place to maintain their sterility.

The 1shot dental x-ray holders in their undamaged, original packaging are not subject to any special considerations for storage or handling. Shelf life in normal conditions is years.

Disposal

Dispose of used holders which pose a risk of infection according to facility clinical waste procedures and applicable locale and state regulations.

1shot dental x-ray holders are manufactured at 300 degrees centigrade from virgin Polysulfone resin in accredited Quality Management System under AS/NZS ISO 9001:2000. 1shot dental holders are an FDA registered medical device.



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