



-Product description, -Sterilization and -Instructions for use,IFU



1shotdental 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 in 3 planes.

Multi use

1shotdental x-ray holders are provided non-sterile. Reusable holders must be cleaned and sterilized prior to use or reuse on patients. Reuse of 1shotdental 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 1shotdental 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 1shotdental x-ray holders.

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

Autoclaving;-including Gravity or Vacuum Sterilizers

- **Temperature and Pressure:** The autoclave must reach and maintain a temperature of 121–134°C (250–273°F) under pressure.
- **Sterilization Time;** 1shotdental X-ray holders can be sterilized at ;-
 - Wrapped items: Typically-30 minutes at 250°F (121°C).
-4 minutes at 270°F(132°C) or 273°F(134°C).
-Drying time Minimum 30 minutes.
 - Unwrapped items: Typically-15 minutes at 121°C and 3 minutes at 134°C. Drying time Minimum 30 minutes.
 - 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.).

1shotdental X-ray holders can be sterilized/autoclaved

repeatedly at cycle parameters of 270/4, 270/5 and 273/4

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 1shotdental holders are one piece.

Dry heat sterilization, boiling, and cleaning solutions are not recommended as sterilization methods for 1shotdental 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 1shotdental 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.

1shotdental 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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