

# BencoDental™

## INSTRUCTIONS FOR USE

### Application of Product

The sterilization pouch is intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider using.

### Descriptions for Product

High Performance White Medical Grade Paper, 52um ±2% blue PET+CPP laminated Film

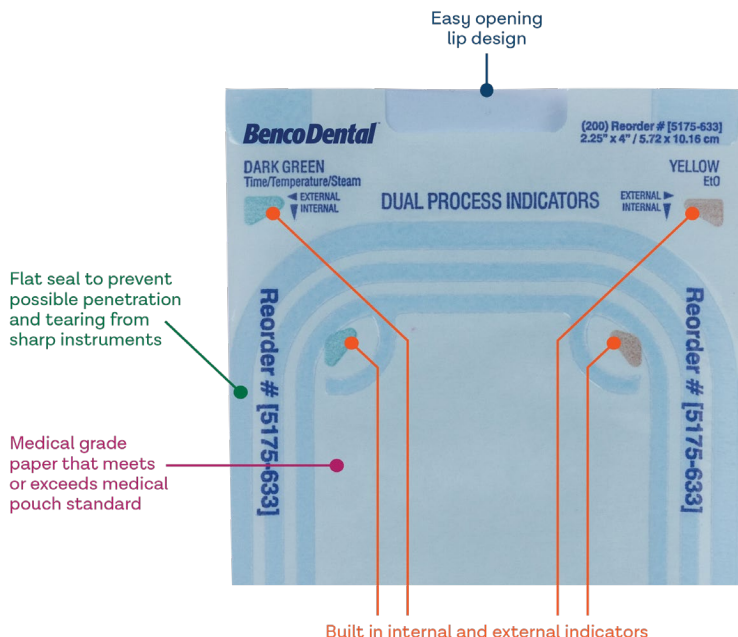
Item No.	Size	Packaging
[5175-562]	3.5" x 9"	500pcs/bx, 4bx/cs
[5175-571]	5.25" x 10"	200pcs/bx, 10bx/cs
[5175-599]	3.5" x 9"	200pcs/bx, 10bx/cs
[5175-606]	2.75" x 9"	200pcs/bx, 10bx/cs
[5175-624]	3.5" x 5.25"	200pcs/bx, 10bx/cs
[5175-633]	2.25" x 4"	200pcs/bx, 10bx/cs
[5175-642]	7.5" x 13"	200pcs/bx, 5bx/cs
[5175-651]	4.25" x 11"	200pcs/bx, 10bx/cs
[5175-660]	3.25" x 11"	200pcs/bx, 10bx/cs
[6910-587]	10" x 14"	200pcs/bx, 5bx/cs
[6910-596]	5.25" x 6.25"	200pcs/bx, 10bx/cs
[6910-603]	12" x 18"	200pcs/bx, 5bx/cs
[6910-621]	11" x 16"	200pcs/bx, 5bx/cs

### Packaging

1. Place items to be sterilized into an appropriate sized pouch. The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration.
2. Carefully press the excess air out of the pouch and ensure there is at least 1-1/4 inches between the adhesive strip and items.
3. After removing the protective strip, seal the pouch by folding the adhesive strip onto the pouch. Apply pressure from the center of the adhesive, towards the edges. Repeat this motion an additional time for extra security.

### Loading the Sterilizer

If you are using several pouches at once, when placing pouches in the sterilizer make sure plastic side of sterilization pouch always faces paper side of adjacent pouch to allow proper air evacuation and sterilant penetration. If possible use a pouch rack to eliminate stacking of the sterilization pouches. Check that pouches are dry upon removal.



## SELF SEALING STERILIZATION POUCHES

### Sterilization Instructions

**Steam:** Pre-vacuum Steam at 134°±2° for about 3 mins, 10 minutes dry time. Sterilization process is completed when indicator changes color.

**EO:** Ethylene Oxide (EO) with a concentration of 500~800mg/L at 55±5°C and 65% ~ 80% relative humidity, sterilization process is completed when indicator changes color.

### Storage for Sterilized Pouches

Please store in a cool and dry environment with relative humidity not exceeding 80%, no corrosive gas, good ventilation and cleanliness. The items should be positioned so that packaging is not crushed, bent, compressed, or punctured so the package integrity is not otherwise compromised.

### Shelf Life

Upon proper handling and storage, the shelf life of a properly processed pouch is 2 years. If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 5 years from the date of manufacture.

### Certificates

The products are registered by FDA under 510(k) Premarket Submission No.: K143637.

Distributed by

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