

INSTRUCTIONS FOR USE – American and Clear Photographic Cheek Retractors

This IFU is applicable to all current and previous generations of the products listed below.

| AO Part Number | AO Brand Name | Saga Dental Brand Name | Color |
|-----------------------|------------------------------------|-------------------------------|--------------|
| 852-760 | American Cheek Retractor | Scandee | Clear |
| 852-761 | American Cheek Retractor | Scandee | Blue |
| 852-762 | American Cheek Retractor | Scandee | Red |
| 852-763 | Clear Photographic Cheek Retractor | Maxee | Clear |
| 852-764 | Clear Photographic Cheek Retractor | Maxee | Clear |

INSTRUCTION FOR USE

DEVICE NAME

This IFU applies to all retractors made from Polypropylene (PP) and Polycarbonate (PC)

INTENDED USE

Saga Dental Supply AS dental retractors are used in dental treatment diagnosed by a trained dental professional to isolate the oral cavity retracting lips and cheeks. The devices are especially designed for use in:

- Orthodontic bonding of brackets
- Interproximal reduction/reshaping
- Clinical photography

INSTRUCTION

To facilitate patient comfort, it may be desirable to apply lip balm or equivalent to the patient's lips prior to inserting the retractors. For Scandee and LC retractors the retractor **must be positioned with the arch facing down towards the chest**. When facing down it may be used to secure the saliva ejector.

1. Hold both extended handles (or the plastic arch in case of LC) and squeeze the retractors together, gently bending the connecting bow in the cheek retractor.
2. The arch provides necessary tension to hold the device in place. Adjust tension by using a rubber band around both the cheek expanders.
3. Instruct the patient to open the mouth. Insert the intraoral expanders of each cheek retractor against the inside of the patient's cheeks. Guide the patient's lips to fit in the curve of each lip retractor.
4. To remove the retractor from the mouth, carefully grasp the left and right cheek handles and remove from the patient's mouth.

- CLEANING CLEAR PC/PP**
1. Use a mild cleanser and a soft brush, or sponge, to clean and rinse of any debris, blood or saliva priori to sterilization.
 2. Place in disinfectant at 90°C program, or
 3. Place in single wrap in a plastic pouch and autoclave at 121° C program.
 4. Dry with a lint free cloth
- CLEANING COLOURED PC/PP**
1. Use a mild cleanser and a soft brush, or sponge, to clean and rinse of any debris, blood or saliva priori to sterilization.
 2. Place in disinfectant at 90°C program, use mild detergent
 3. Dry with a lint free cloth

NOTE

Clear polycarbonate (PC) products will become opaque and develop cracks with time when heat treated/autoclaved. This is in the nature of the material when it has been autoclaved for several times.

Some chemicals and cleansers may make the retractor brittle and cloudy.

To maintain a long lifetime of our coloured polycarbonate (hard material) should be cold sterilized.

Our clear polycarbonate (PC) and polypropylene (PP) retractors **must be autoclaved at temperatures up to 121°C**

STORAGE & SHELF LIFE

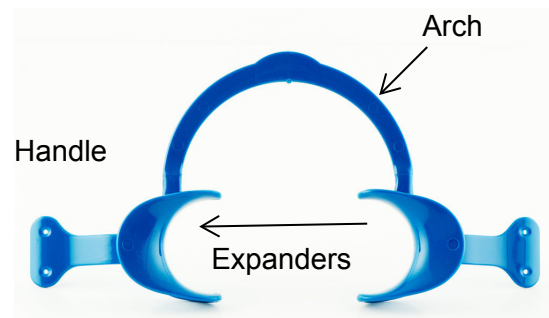
- Due to sterilization process, it will change color, clear will become opaque, bubbles and cracks will develop. Such items should be discarded.
- Plastic fatigues over time and daily use can cause breakage.

MATERIAL DATA

Please refer separate Material Data Sheet covering our Polycarbonate and Polypropylene products.

DISPOSAL

The device is made of recyclable polypropylene or polycarbonate. Saga Dental Supply AS suggests the product to be disposed of according to country or state regulation.



| Document ID | IFU Version | Author | Owner | Page |
|---------------|----------------|------------|---------------|--------|
| Retractor IFU | 2023-10-09/V10 | Nils Kumar | Swadesh Kumar | 1 av 1 |