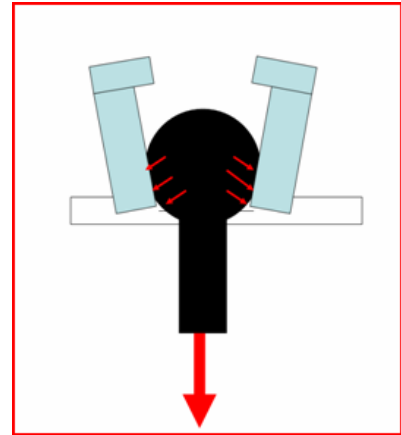


The picture to the right shows what was happening in the faceplate socket during mask usage with the old style ball clip:



The investigation also found that outside contaminants such as **hand lotion**, **extremely hot water** and **citrus cleaners** could accelerate the weakening of the clear polycarbonate faceplate and socket.

#### Why is the new Mushroom-shaped Ball Clip Better?

This new ball clip is made of a new softer material, with a mushroom shaped head and more ergonomic grip area as compared to the old style ball clip. Our extensive testing has shown that the new mushroom shaped design will result in a significant increase in the life of the ball socket area as compared to the original design. **How?**

- The new [mushroom-shaped design](#) [better distributes](#) the stresses caused during mask removal, [deflecting](#) that stress to the [body](#) of the mask faceplate [instead of the socket area walls](#).
- The [softer ball clip material](#) on the new clip [better absorbs](#) the stresses caused by mask removal, thereby reducing the stresses in the socket area even further.
- Additionally, the new ball clip has a much larger grip area and raised bumps. This greatly improved ergonomic design was created with ease of use in mind for the normal patient and for users with limited hand dexterity.

#### Important: Visual Difference in the Ball Clips with Use

One result of using the softer material in the new ball clip is that its [shaft will show wear](#), evidenced by visible nicks. Please let your customers know that this is [normal and entirely expected](#). Also, inform them that the nicks [will not cause clip breakage in any way](#).

Here is a picture of the shaft area that shows normal wearing after normal usage:



**Normal Usage Picture**

Below is another picture of the shaft that shows the result of one of our validation tests. This test estimated nearly 8 years of usage with the socket area in the EXACT same location on the shaft of the ball clip, as evidenced by the deep groove. Even this worst case scenario was not enough to break the shaft:



**Wear Test Picture**

### **How much socket area life improvement can be expected?**

- Our tests have shown that the new design will increase the socket area life by over 10 times.

### **Call to Action:**

- Show your customers the new mushroom shaped ball clip. Explain how it reduces stress in the socket area and significantly improves its life expectancy.
- Offer the RP kits so that they can begin to use the new clips while depleting their existing inventory. They can hand out the new mushroom-shaped ball clips when they are distributing their existing, old style clip inventory. [The RP kits will be provided free of charge until the end of June.](#)
- While discussing the changes, it is a great opportunity to provide your customers with some ball clip handling tips, see the appendix.

You should receive several mushroom-shaped ball clip RP kits in the next week. When you deplete your stock, you can order additional RP kits via Customer Service. To prevent large backorders while we build up our RP inventory, additional orders will be limited to 100 RP kits until the implementation is completed. PN 1009723.

Again, the new clips will be included in all ComfortGel, ComfortFull 2 and ComfortSelect masks with lot codes of 070309 and later. Lot codes represent dates in the format YYMMDD.

Best Regards,

Jason Proch

Laurie Scott

## Appendix

### Tips for Clip Installation and Removal

#### **To Install the Ball Clip:**

Place the head of ball clip against the bottom of your finger.

Use the tip of your finger to feel for the socket area of the mask.

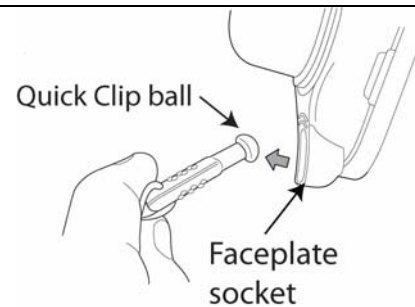
Then use your finger to depress the tip into the socket until it clicks into place.



#### **Methods to Remove the Ball Clip:**

##### **Clip Removal Tip 1:**

Grasp the body of the ball clip and gently pull it out of the socket away from the face (do not attempt to pull the clip through the socket).



##### **Clip Removal Tip 2:**

Slide your hand between the headgear strap and your cheek with your palm against your cheek.

Gently move your hand outward away from your face. The ball clip will disengage.

