



URGENT FIELD SAFETY NOTICE

It has recently been reported that an unattended child aged 7 months has required treatment to remove an earmould from the larynx. This is the first reported incident of its kind, the likelihood of such event is considered extremely low* (*a single reported incident in a year represents less than 0.01% of paediatric provision) and on this occasion there was no long-term injury. However, from the time a child starts picking up things with their fingers until the age of 4 or 5, we need to be vigilant about choking hazards. Children under 4 are the most likely to choke on something. This is partly because they tend to explore their world by putting things in their mouth. Starkey Laboratories have worked with clinicians to provide a set of options that can be used by clinicians to mitigate any risk.

Earmoulds are designed to be removed from hearing instruments. Removal is desirable as it allows for a maintenance and hygiene routine essential for consistent performance and benefit. Often earmould tubing is stretched for ease of fit onto the hearing aid elbow, clinicians are encouraged to avoid excessive stretching and to check the security of fit as part of the dispensing routine. Tubing and fit should be monitored for degradation and tubing replaced if required.

Earmould tubing is designed to be removed from an earmould so that it can be replaced as part of a long term maintenance routine also to ensure consistent performance and benefit. Up until the age of four there is significant growth which means that earmoulds may be discarded sooner than replacing of earmould tubing becomes necessary. In these circumstances clinicians may consider it a reasonable option to fix the tubing within an earmould. Starkey Laboratories have previously communicated that orders may be marked "**Glue-In-Tube**" to receive this free of charge option. Clinicians should be mindful of the obvious impact on standard cleaning routines when selecting this option.

3D Printing of silicon earmoulds means that Starkey Laboratories can provide clinicians with a highly innovative alternative to the "Glue-in-Tube" option. Starkey technicians can now produce a silicon **earmould and tubing printed as one piece**. This means that the tubing is no longer a separable item. The production technique also improves candidacy and fit because we no longer require tubing in the meatus allowing fitting to the narrowest of ear canals. The absence of internal tubing also facilitates acoustic enhancements because the sound path can be designed and printed as required and is no longer limited by tubing dimensions.

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