




Product Documentation

Impressions of children's ear canal
using addition mini Junior

addition mini Junior

Ear impression silicone for pediatric adaptations

DETAX




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1. Introduction

The ear is the first of the sensory organs to fully mature during foetal development. In fact it is almost fully developed by the 22nd week of pregnancy ¹⁾. In the mother's womb, a child begins to notice various sounds and respond to appropriate stimuli, thus already exhibiting an awareness of its surroundings. The major developmental processes in the evolution of hearing (maturation of the auditory system) take place during the first four years of life. During this time, the requisite links to the relevant brain cells are created and programmed. Good hearing is extremely important to linguistic development and therefore also plays a vital role in psychological, emotional and social




development ²⁾. The inability to hear creates a void between humans and their environment, considerably limiting their scope of communication. Thus it is very important to identify and treat any hearing disorders as early on as possible ³⁻⁴⁾. For this reason, auditory screening of neonates, with the aim of identifying any potential defects, has become in the past few years common practice ⁵⁾. If abnormalities are found, further tests are performed and if necessary an appropriate hearing aid prescribed. To ensure that the hearing aid is accepted and worn as often as possible, it must be virtually imperceptible and wearable for long periods. If it exerts any pressure, or even pain, then it will be rejected and go unused – factors which limit, if not prevent its success altogether. The ear mould must therefore guarantee a perfect fit. In order to provide a child with a customised ear mould, a perfect impression has to be taken of



the outer ear and auditory canal. This is the first and foremost step in the manufacture of a perfectly formed ear mould. To obtain such an impression, a formulation is introduced into the auditory canal which is initially viscous but hardens after a few minutes into a soft, elastic mass. Previously, the same impression materials were used as in adults but were suitable only to a limited extent for the little ears of children. Children are not simply mini adults, but deserve special attention when it comes to the quality and application of ear impression materials.

addition mini Junior is the first impression material designed specifically for taking impressions of children's ears. It is not only the material itself



that has been modified – the applicators have also been miniaturised. Hence the material has exceptional properties, not only due to much better viscosity, more rapid hardening and improved demouldability, but also because it is available in small, handy dual cartridges which are easy to extrude.

2. Characterisation

addition mini Junior is an impression material designed specifically for children's ears, based on two-component, addition curing silicone. During development, particular emphasis was placed on obtaining a perfectly viscous consistency which would render the material easy to apply via the cartridges, ensuring that it flows readily into the small auditory canals and produces accurate



impressions. The setting reaction is triggered by mixing the two components at the time of application. The moulding compounds polymerise in the ear in a very short time, producing a soft, elastic and highly stable mass which is simple to remove.

addition mini Junior has been designed for children. Children find the bright, child-friendly colour and lemonfresh aroma attractive, thereby reducing or even banishing any possible fears regarding the moulding procedure. To keep the force to a minimum during application, use of the delivery device ("Mixing gun mini") is recommended.

Due to their fluidity, the material can also be applied without the extrusion device, since little

force is required to extrude the material. One innovation is the direct application from the dual cartridge, without the mixing gun, which makes handling of the product particularly easy. Parents and children find the direct application from the mini syringe less inconvenient and "risky" than with the large, conventional cartridge plus mixing gun.



Fig. 1: minimix cartridge with plunger



3. Presentation

The product is available in dual-chamber minimix cartridges. The product is delivered either directly using the supplied plunger (Fig. 1) or the delivery device which can be ordered separately (Fig. 2).



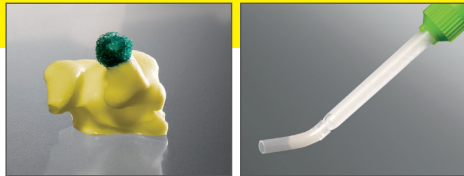
Fig. 2: Systems compared cartridges/delivery devices

The greatly reduced dimensions of the cartridges permit not only simple and precise handling, but also mean that children will not be frightened.

The two components are blended homogeneously by using static mixers, thereby preventing dosage errors from the outset. The diameter of the static mixers is adapted to the dimensions of the child's auditory canal.




Fig. 3: Mixer for adults on the left, for children middle and right (with Flexi tube)



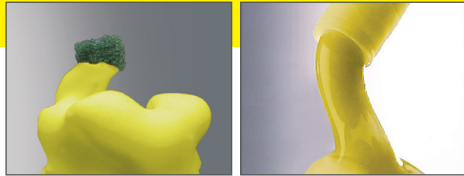
To compare, Fig. 3 depicts a small mixer ("mixing cannula minimix") next to one which is usually used in adults. A soft silicone tube (Flexi tube, Fig. 3) can be mounted on the hard mixer for ears that are particularly sensitive (babies).

4. Flowability

High flowability guarantees that the moulding compound readily flows into the narrow auditory canals, filling them completely and producing the desired mould without any pressure whatsoever. A perfectly accurate impression of the auditory canal can thus be made. This, in turn, is the most important criterion for producing an ear



mould that can actually be positioned perfectly and exerts no pressure of any kind. Ear impression materials available at present for paediatric use were developed for use in adults and in most cases cause pressure to develop in the auditory canal. This applies in particular to kneadable moulding compounds. During the relatively long mixing time required by kneadable materials, the immediate onset of the setting reaction leads to curing of the material before it has even been introduced into the auditory canal ⁶⁾. Thus the viscosity is increased and pressure intensified. A build-up of pressure causes the soft, cartilaginous tissue of the ear to become deformed – this deformation is consolidated by vulcanisation of the moulding compound. Ear moulds produced on the basis of such deformations will be too large, uncomfortable to wear, and will lead to the progressive but also undesirable and even damaging expansion of the



auditory canal, since the tissue will adapt and yield to the change in environment ⁷⁻⁸⁾. Pressure will not result from a very fluid material, meaning that perfectly formed ear moulds are created during the manufacturing process which cause no pressure and are therefore more readily accepted and worn. Hence it is worthwhile immediately applying a film over the impression material once introduced and inclining the head somewhat in order to prevent the material from slowly escaping.

The flow properties of materials are measured in terms of viscosity. Low viscosity implies that the flow properties are good. Fig. 4 compares the viscosities of **addition mini Junior** against the viscosity of **addition supra**[®] (a slightly flowing

material for taking ear impressions in adults). It is evident that the viscosity of both materials for paediatric impressions is up to 3 times lower than that of the equivalent material used in adults.

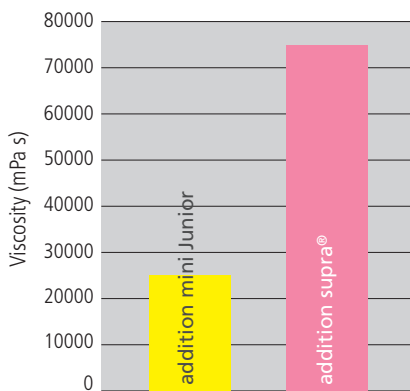


Fig. 4: Viscosities of impression materials for children and adults compared



Achieving accurate impressions, even from the smallest of auditory canals, is child's play at such low viscosities. Nevertheless, the material does not run out of the ear due to its thixotropic behaviour.

5. Extrusion force

To ensure that the impression materials can be introduced into the auditory canal without force and with confidence, the extrusion force required must be kept to a minimum. The extrusion force is the strength which is needed to press the two materials through the mounted static mixer using a plunger. Such a force can be determined using a materials testing system (Zwick/Roell Z0.5) and is presented in

Fig. 5, again compared against **addition supra**[®]. It shows that the extrusion force for the paediatric impression material is much lower. An extrusion force of 50 N corresponds to a weight of 5 kg and allows the cartridge with supplied plunger to be

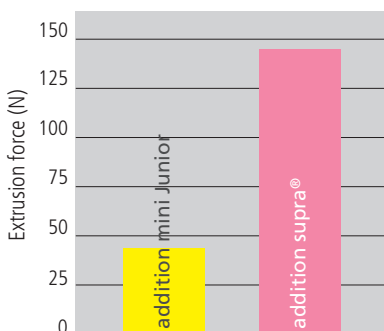
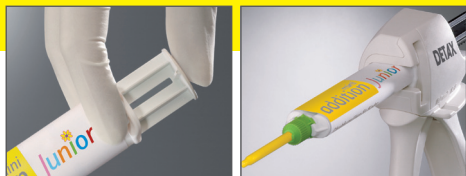



Fig. 5: Extrusion forces for impression materials from the minimix cartridge and when using the static mixer



used by hand. If this still appears to be too difficult, the handy „mixing gun mini“ can be used in order to achieve effortless impressions. At a force of 140 N, on the other hand, a material such as **addition supra**[®] cannot be pressed through the smaller mixer by hand. The low extrusion force results from the good flow properties of **addition mini Junior**, facilitating the use of small and thinner mixing cannulas.

6. Time in the ear/Setting time

Children are generally very active and are unable to sit still for long, so a short setting time or time in the ear is highly advantageous. In addition, children are



happy if they can get the procedure over and done with as quickly as possible. **addition mini Junior** has a time in the ear of 2 minutes - roughly one minute less than the most rapid materials in adults, which have a time in the ear of about 3 minutes. Due to the very rapid setting reaction, which in the warm environment of the auditory canal is even quicker (thermocontrolled) than outside the ear, the viscosity of the material increases very rapidly so that „permeation“ of the impression plug or swab, and consequently contact with the eardrum, need not be feared.

7. Hardness

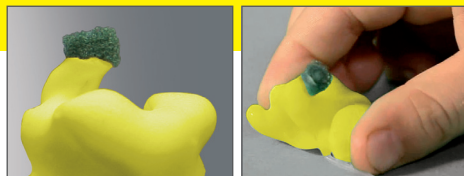
Once set, the impression must be removed from the ear. To make this easier, a softer and thus more



pliable consistency is required. A characteristic feature of **addition mini Junior** is its low hardness, rated on the Shore scale as A 25. The impressions are therefore flexible enough to be removed from the auditory canal without force and without causing discomfort to the child. Comparable impression materials for adults, on the other hand, are much harder, with Shore ratings of A 35 to 40. Owing to this reduced hardness, the impressions are difficult to adapt with conventional cutters, but can be shaped as necessary with scissors, a scalpel or grinding caps.

8. Tear resistance

Aside from low hardness, the cured impression materials must also possess high mechanical strength (tear resistance = strength required per mm sample thickness to tear the material) in order to prevent tearing on removal and deposits possibly being left in the auditory canal. The tear resistance of the impression materials has been determined in accordance with DIN ISO 34-1 and the results are presented in Fig. 6. **addition mini Junior** also performs exceptionally well in this test, achieving values which are more or less equivalent to the materials used in adults. Also, the values for the new paediatric impression material are much higher than those measured with kneadable moulding compounds (3-4 N/mm) or a similarly soft material (competitor "Xsoft Shore A 25" 3.8 N/ mm), for instance.



In addition to the strength required to resist tearing, moulding compounds must exhibit the maximum possible elongation when exposed to the risk of



Fig. 6: Tear resistance of impression materials

tearing. The greater this elongation, the more elastic the material becomes and the easier it is to remove. This is demonstrated quite clearly in Fig. 7, where the samples of **addition mini Junior** and the competitor product "Xsoft Shore A 25" are

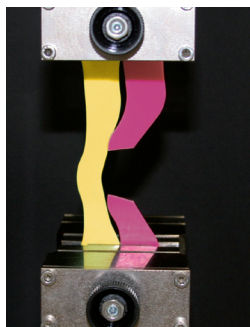



Fig. 7: addition mini Junior (intact) and Xsoft Shore A 25 (torn) exposed to equal force and tensile load



simultaneously exposed to a tensile load in the same way as when measuring tear resistance.

Where as “Xsoft Shore A 25” has already been torn apart, **addition mini Junior** is still resistant to the force and strain applied.

If **addition mini Junior** and “Xsoft Shore A 25” are stretched to 280% of their original sample lengths, **addition mini Junior** is seen to return to its original length when the load is released. The elongated sample of “Xsoft Shore A 25”, on the other hand, does not return to its original length (see Fig. 8).

Furthermore, whitening of the elongated area (known as stress whitening) can be seen, suggesting that irreversible microcracks have developed ⁹⁾.

Therefore, "Xsoft Shore A 25" is unable to deliver a faithful impression after being subjected to tensile strain. **addition mini Junior**, meanwhile, does not exhibit any stress whitening after being exposed to tensile strain, and returns to its original shape.

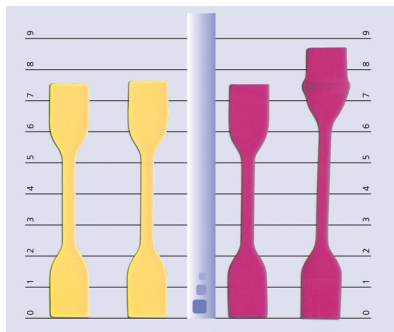



Fig. 8: Non-elongated and elongated samples of addition mini Junior (left) and Xsoft Shore A 25 (right)

9. Deformation under pressure and Recovery after deformation

Two further important parameters that describe the quality of an impression material are deformation under pressure and recovery after deformation, factors which are determined in accordance with DIN standard EN ISO 4823. Deformation under pressure refers to the percentage of deformation of a specimen which is deformed under the influence of a specified force. The higher this value, the easier it is for a material to be deformed.

addition mini Junior is at the top of the pile at 10%. This high level of deformability is one of the main reasons why removal of the impressions is easy and straightforward. To replicate the shape of the auditory canal precisely, an impression material must return to its original state after having



been deformed under pressure. This is known as recovery after deformation, and is likewise achieved by **addition mini Junior** with peak scores of 99.8%. Thus it is guaranteed that following deformation the impression regains its original shape and is able to deliver a perfect reproduction of the auditory canal.

10. Toxicology

addition mini Junior contains only components which at their applied concentrations are toxicologically safe. This has also been confirmed by biological tests performed in accordance with ISO standards. The cytotoxicity test (L929 proliferation, EN ISO 10993-5) was passed with lowest inhibition of proliferation of < 1%. Hence, the material is decidedly non-cytotoxic and biocompatible.




11. Application (tips and tricks)

addition mini Junior is applied in the same way as the materials used in adults; however, particular attention should be paid to the following points due to the smaller dimensions and higher degree of sensitivity in children:

Before taking an impression, the ear must be thoroughly examined and cleaned. No impression must be taken if the eardrum (valid also for tubes) is damaged or perforated.

An impression plug must be placed in front of the ear drum and its position checked prior to introducing the impression material. It is advisable



to use vented impression plugs that prevent the formation of negative pressure on removal.

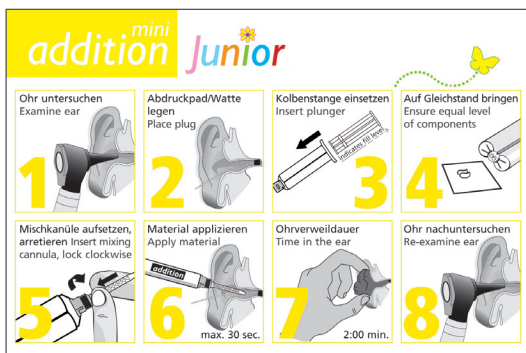
Before attaching the mixing cannula, the two components must be equalled out, i.e. material expelled from the cartridge until it begins to emerge from both openings. The extruded material is wiped away and the mixer then mounted and fixed into place. Material is then pushed through the mixer and the initial, roughly pea-sized quantity discarded. If this procedure is not heeded, then possibly only one component may reach the auditory canal when application is commenced, or an insufficient quantity of the second component may be mixed with the first, meaning that the material may fail to harden or only partly set and remain in the ear. A soft silicone tube (Flexi tube) can be mounted on the hard mixer for ears that are particularly sensitive.



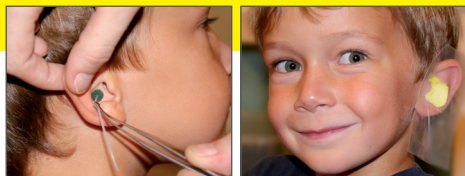
The low viscosity that facilitates filling of the narrow auditory canal may in some cases result in the need for a film covering and/or inclination of the patient's head (especially if the ears are large, or in adults).

Once the impression has been removed, the ear must again be checked for integrity and cleanliness.

The impression can be refined with a scalpel or scissors. To remove thin layers from the surface, grinding caps should be used rather than metal cutters.



flowchart



12. Technical data

Characteristic	addition mini Junior
Colour	yellow
Odour	lemon
Viscosity (mPa*s)	25000
Dwell time (min.)	2
Hardness (Shore A)	25
Tear resistance (N/mm)	4,8
Deformation under pressure (%)	10
Resetting after deformation (%)	99,8
Linear dimensional change (%)	< 0,2

13. Sources

- 1) Gerhard Friedrich; Wolfgang Bigenzahn; Patrick Zorowka; „Phoniatrie und Pädaudiologie“; Verlag Hans Huber Bern 2008, p. 339
- 2) Susanne Nussbeck; „Sprache - Entwicklung, Störungen und Intervention“; W. Kohlhammer GmbH Stuttgart 2007, p. 87
- 3) Jürgen Wendler, Wolfram Seidner, Ulrich Eysholdt; „Lehrbuch der Phoniatrie und Pädaudiologie“; Georg Thieme Verlag Stuttgart 2005, p. 367
- 4) Wiesner T, Bohnert A, Massinger C; „Konsenspapier der DGPP zur Hörgeräte-Versorgung bei Kindern“ verabschiedet auf der DGPP-Jahrestagung am 12.9.2002 in Erlangen, Version 1.1 vom 30.3.2003
- 5) Beschluss des Gemeinsamen Bundesausschusses über eine Änderung der Kinder-Richtlinien: Einführung eines Neugeborenen-Hörscreenings, 2008
- 6) M. Kunz, „Otoplastik: Die Abformung – Knetmasse oder Kartuschenmaterial?“, Hörakustik 12, 2010 p. 14
- 7) U. Voogdt (-2); „Otoplastik,“ Median-Verlag von Killisch-Horn GmbH, 2005 p. 150
- 8) U. Voogdt, „Okklusionseffekt und Vermeidungsstrategien“, Audio infos 123, Juli 2011
- 9) F. Johannaber, W. Michaeli, „Handbuch Spritzgießen“ Hanser Verlag München 2004, p. 63

Ordering information

addition mini Junior

Standard packing **03439**

4 x 10 ml minimix cartridge
8 mixing cannulas minimix, green
1 piston, flowchart

Refill packing **03440**

8 x 10 ml minimix cartridge
1 piston

Mixing cannulas **03446**

25 pcs. minimix, green 1:1

Mixing gun mini **03447**

for minimix cartridge

Flexi tube **03448**

20 cm for minimix cannulas

Vented impression plugs **03449**

24 pcs., Ø 7 mm

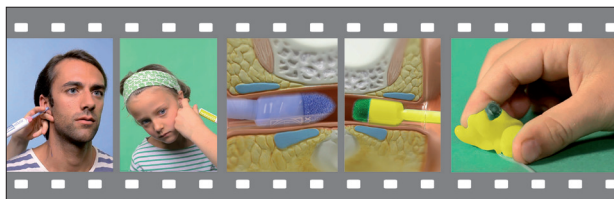


addition mini Junior

Precision ear impression silicone



- low viscous, smooth consistency, non-sticky!
highly thixotropic
- no pressure build-up, no displacement of soft tissue,
no unwanted run-off



<https://youtu.be/IQCwHqPhEBM>

the first ear impression material for kids



for pediatric adaptions



- child friendly: extra short time in the ear (2 min.!), jelly bean scent, biocompatible, easy to remove
- perfectly adjusted for pediatric adaptions
- supplied in handy minimix cartridges, easy to use

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