



Product Documentation

Taking impressions of the outer ear
in infants and children with
addition mini Junior & addition mini Sensitive

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 and **addition mini Sensitive** are the first impression materials designed specifically for taking impressions of children's ears. It is not only the materials themselves that have been modified – the applicators have also been miniaturised. Hence the materials have exceptional properties, not only due to much better viscosity, more rapid hardening and improved demouldability, but also because they are available in small, handy dual cartridges which are easy to extrude.

2. Characterisation

addition mini Junior and **addition mini Sensitive** are impression materials designed specifically for children's ears, based on two-



component, addition curing silicones. During development, particular emphasis was placed on obtaining a perfectly viscous consistency which would render the materials easy to apply via the cartridges, ensuring that they flow readily into the small auditory canals and produce 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 a somewhat greater consistency and has been designed for older children and adolescents. Children find the

bright, child-friendly colour and jelly bear 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.

addition mini Sensitive has been designed specially for babies, infants and allergy sufferers. When designing this formulation, we deliberately avoided using any non-essential ingredients in order to rule out the risk of allergies. The material contains no conventional fillers, colourings, fragrances or preservatives, and is therefore suitable for allergy sufferers.

Due to their highly fluidity, the materials 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.

3. Presentation

Both products are available in dual-chamber mini-mix cartridges. The product is delivered either directly using the supplied plunger (Fig. 1) or the delivery device which can be ordered separately (Fig. 2). The greatly reduced dimensions of the cartridges permit not only simple and precise

handling, but also mean that children will not be frightened by the appearance of the devices.

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. 1: minimix cartridge with plunger



Fig. 2: Systems compared cartridges/delivery devices



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).



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

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.

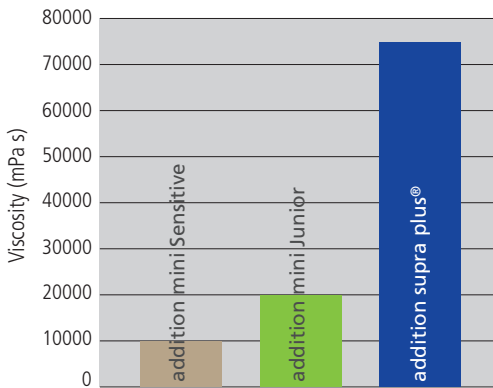


Fig. 4: Viscosities of impression materials for children and adults compared



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** and **addition mini Sensitive** against the viscosity of **addition supra plus**[®] (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 7 times lower than that of the equivalent material used in adults. Achieving accurate impressions, even from the smallest of auditory canals, is child's play at such low viscosities. Nevertheless, the materials do not flow straight out of the ear. This is ensured by the balanced thixotropic properties which develop as soon as the components have been mixed.

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 plus**[®]. It shows that the extrusion force for paediatric impression materials 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 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 plus**[®] cannot be pressed through the smaller mixer by hand. The

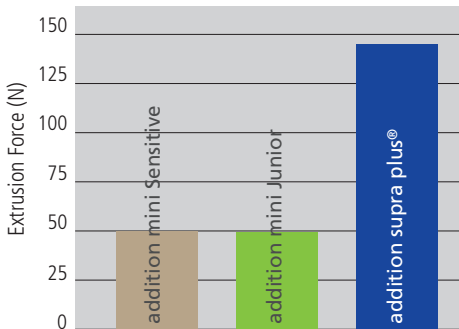


Fig. 5: Extrusion forces for impression materials from the minimix cartridge and when using the static mixer

low extrusion force results from the good flow properties of **addition mini Junior** and **addition mini Sensitive**, 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** and **addition mini Sensitive** have 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** and **addition mini Sensitive** is their 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** and **addition mini Sensitive**



also perform 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 materials are

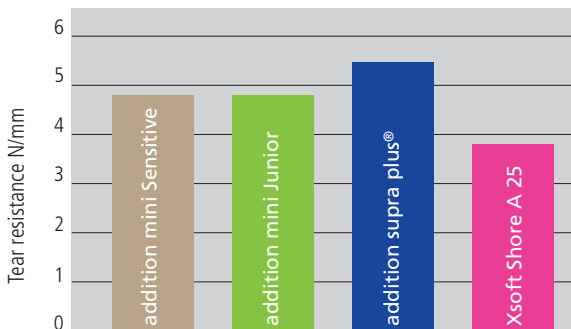


Fig. 6: Tear resistance of impression materials

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.



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

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

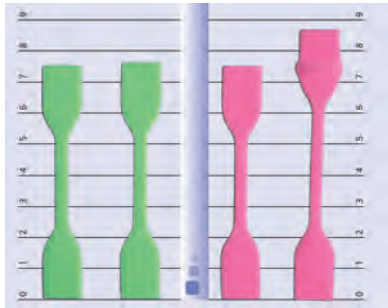


Fig. 8: Non-elongated and elongated samples of addition mini Junior (left) and Xsoft Shore A 25 (right)

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.

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 and **addition mini Sensitive** are 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 both paediatric impression materials 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 and **addition mini Sensitive** contain only components which at their applied concentrations are toxicologically safe. This has also been confirmed by biological tests performed in accordance with ISO standards (Fig. 9). The cytotoxicity test (L929 MEM Elution Test, ISO 10993-5) was passed with high viability levels (89.9% and 94.8%). Hence, both materials are decidedly non-cytotoxic and biocompatible. By omitting any non-essential ingredients, the risk of allergic reactions to **addition mini Sensitive** is further reduced, making it an ideal product also for adult allergy sufferers.

STUDY SUMMARY

99.32 % viability was observed for the L-929 mammalian cells exposed to the test item at the 41 hours observation. The observed cellular response obtained from the positive control extract (1.99 % viability) and the negative control extract (100.40 % viability) confirmed the suitability of the test system. The test item, OTO addition junior (avoma) (Batch: V 110952-1), is considered non-cytotoxic and meets the requirements of ISO 10993-5.

APPROVAL

TE number: TE 11992
Study number: 11-B2784-N1

Title: *In-vitro* Cytotoxicity Assay on L-929 mouse fibroblasts

Study Director: Ir. Peter Cornelis
Study Director's address: Toxikon Europe NV, Rommelsestraat 12, B-3001 Leuven, Belgium



Ir. Peter Cornelis
Study Director



Date

This signed statement indicates that the report has been reviewed by the Quality Assurance Unit and accurately reflects the raw data developed during the study.



Marc De Buyser
Quality Assurance



Date

Fig. 9: Cytotoxicity test certificate



11. Application (tips and tricks)

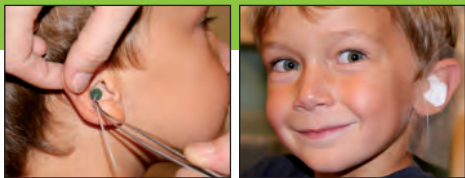
addition mini Junior and **addition mini Sensitive** are applied in the same way as the materials used in adults; however, particular attention should be paid to the following points due to the smaller dimensions and higher degree of sensitivity in children:

Before taking an impression, the ear must be thoroughly examined and cleaned. No impression should 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, thereby facilitating the procedure.

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.

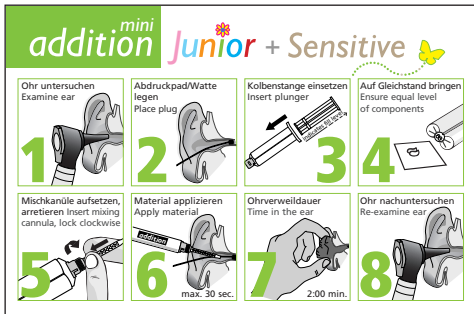


A soft silicone tube (Flexi tube) can be mounted on the hard mixer for ears that are particularly sensitive (babies).

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 (in every standard packing)

12. Technical data

Charakteristik	addition mini Junior	addition mini Sensitive
Colour	green	white
Odour	gummi bear	none
Viscosity (mPa*s)	20000	10000
Dwell time (min.)	2	2
Hardness (Shore A)	25	25
Tear resistance (N/mm)	4,8	4,8
Deformation under pressure (%)	10	10
Resetting after deformation (%)	99,8	99,8
Linear dimensional change (%)	< 0,2	< 0,2

13. Sources

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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, flowchart



Mixing gun mini **03447**
for minimix cartridge

Mixing cannulas **03446**
25 pcs. minimix, green 1:1

addition mini Sensitive

Standard packing **03436**

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

Refill packing **03437**

8 x 10 ml minimix cartridge
1 piston, flowchart



Flexi tube **03448**
20 cm for minimix cannulas

Vented impression plugs **03449**
24 pcs., Ø 7 mm



DETAX

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