

PATIENT INFORMATION LEAFLET: AURAL VENTILATION TUBES



This Patient Information Leaflet ("PIL") is designed to provide information about Exmoor Medical Aural Ventilation Tubes ("Grommets") bearing product codes E31, E101, E102, E103, E104, E106, E107, E108, E109, E114, E32, E56, E58, E60, E64, E110, E111, E115, E116, E51, E52, E53, E54, E57, E59, E61, E153, E154

This leaflet is also available in digital format at:
vernacare.com/brands/exmoor

"What are Grommets?"

Grommets are very small plastic tubes, which sit in a hole in the eardrum. They let air get in and out of the ear. This keeps the ear healthy.

Why are Grommets Used?

Some people get fluid behind the eardrum. This is sometimes called 'glue ear'. It is very common in young children, but it can happen in adults too. We don't know exactly what causes glue ear. Most young children will have glue ear at some time, but it doesn't always cause problems. We only need to treat it if it is causing problems with hearing or speech, or if it is causing lots of ear infections.

How are grommets put in?

The grommets are placed in the eardrum under a short general anaesthetic and the procedure is usually performed as a day case admission to hospital. The operation is carried out down the ear canal so there are no cuts to see on the outside of the ear. A small opening is made in the eardrum using a microscope to magnify the area and the fluid is sucked out of the ear with a fine sucker. The grommet is then placed in the opening in the eardrum. The procedure takes between ten and twenty minutes."

How Long Do Grommets stay in for?

Grommets typically fall out by themselves, but they may stay in for the following periods, which are dependent on the design of the grommet, the patient's individual circumstances, and subject to periodic reviews of your progress by your physician:

- 4 to 9 months: **Product Codes:** E31, E101, E102, 103, E104, E106, E107, E108, E109, E114
- 12 to 18 months: **Product Codes:** E32, E56, E58, E60, E64, E110, E111, E115, E116
- >24 months: **Product Codes:** E51, E52, E53, E54, E57, E59, E61, E153, E154

"What are the alternatives to grommets?"

Steroid nasal sprays may help some children if they have nasal allergy; Congestion in the nose caused by allergy may affect the normal function of the nose and ears. Antibiotics, antihistamines and decongestants do not help this type of ear problem. Alternative treatments, such as cranial osteopathy are not helpful. Using a nasal balloon to open the tube to the ear may help older children if used regularly. Taking out the adenoids may help the glue ear get better, and your surgeon may want to do this at the same time as putting grommets in. A hearing aid can sometimes be used to treat the poor hearing and speech problems that are caused by glue ear. This would mean that your child would not need an operation.

What about ear infections?

Most people with grommets do not get any ear infections. If you see yellow fluid coming out of the ear, it may be an infection. It will not be as sore as a normal infection, and your child won't be as ill. In this situation we advise you to take your child to see your GP. If you get some antibiotic ear drops from your GP doctor, the problem will quickly settle. Some doctors may give antibiotics by mouth instead of antibiotic ear drops. Ask your GP or ENT doctor for help if infections become troublesome"

What precautions are needed after grommets are inserted?

After insertion of grommets, the ears should be kept dry for the first four weeks. Patients are strongly advised to attend regular follow-up appointments with their physician until such time that the grommet has fallen out naturally, or has been removed, from the ear.

If you notice a yellow discharge from the ears, this may be a sign of infection, and you should consult your General Practitioner immediately for advice. If any discomfort, discharge or deterioration in hearing is experienced consult your physician immediately

What are Grommets Made From?

Your physician will recommend the specific grommet which he believes will be the most suitable. Exmoor Medical Grommets are manufactured using the following materials:

- PTFE (Polytetrafluoroethylene): **Product Codes:** E101, E102, E103, E104, E106, E107, E108, E109, E110, E111, E114, E115, E116
- HDPE (High Density Polyethylene): **Product Codes:** E31, E32, E59, E60, E64
- Silicone: **Product Codes:** E51, E52, E53, E54, E56, E57, E61, E153, E154

What are the RISKS/SIDE EFFECTS of Grommets

There is a potential risk of the following complications: Infection and/or potential scarring of the ear drum ("tympanosclerosis"). A very small risk that the grommet will be rejected or that there will be a residual perforation of the ear drum.

Certain drugs may increase the risk of perforation of the ear drum.

- The grommet may require surgical removal
- There is a risk of deterioration in aural function
- The grommet may migrate into the middle ear, which would require a surgical procedure to remove or reposition it
- More than one grommet insertion procedure may be required
- Occasionally, once a grommet has naturally come out, a hole may be left in the ear drum. This normally heals over time, but sometimes a further operation is required to close the hole
- A discharge from the ear may occur after the procedure
- A higher risk of complications for patients who also have other clinical conditions, such as cleft palate.

PRODUCT HANDLING INSTRUCTIONS

Pack contents are sterile providing that its packaging remains intact. The product **MUST NOT** be used if its packaging is not intact. This product **MUST NOT** be resterilised. Open the packaging with great care, in order to avoid spilling the device inadvertently, and remove the grommet aseptically.

RECOMMENDED STORAGE CONDITIONS

Store in a dry environment. Avoid extremes of temperature and humidity. Optimal storage conditions are between 10 - 35°C and 20 - 80% relative humidity. Keep out of direct sunlight.

DISPOSAL

Follow local policies and procedures for disposal of clinical waste

This product may only be used, or sold, by, or on the order of, a physician

The "grommets" otherwise known as 'ventilation tubes' or 'PE (Pressure Equalisation) tubes' described in this PIL are single use devices, they have been sterilised and are ready for use.

Warnings:

Do not reuse in whole or in part. Any reuse will be deemed misuse and may result in infection of a patient, user or third party. Do not use if "use by" date is expired. Refer to Unit/Lot Number label.

Do not use if sterile pack is breached, damaged or contaminated.

In the event of a serious product related incident, or to request additional product information or a further copy of this leaflet, contact the manufacturer (Exmoor Plastics Ltd) and inform the TGA www.tga.gov.au

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Email: sales@exmoorltd.com

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A glossary of symbols seen on the product packaging can be accessed at: <https://www.vernacare.com/symbols-glossary>

¹ ENT conditions and procedures – Grommets, accessed at: <https://www.entuk.org/patients/conditions/5/grommets>