

Manufacturer:
TECHNOVENT LIMITED
Unit 5, York Park, Bridgend Industrial Estate
Bridgend, CF31 3TB, UK
Tel: +44 (0) 1656 768566
www.technovent.com



INSTRUCTIONS FOR USE

A-100, A-564, G531 Sealants

PRODUCT DESCRIPTION:

A-100, A-564, G531 Sealants are a range of 1 part acetoxy adhesive silicones used to seal external colours onto prostheses.

INTENDED USE:

A-100, A-564, G531 silicone sealants are designed to seal extrinsic colours on to external maxillofacial prostheses. They can also be used to repair cured silicone rubber in certain circumstances.

INTENDED USERS:

A-100, A-564, G531 prosthetic sealants are intended for professional use only, in particular maxillofacial prosthetists who have experience and training in the use of silicone rubber systems for external prostheses.

Proper procedures and techniques are the responsibility of the medical professional. They must evaluate the appropriateness of the procedure based on personal training and experience as applied to the patient at hand.

INTENDED PATIENT GROUP:

A-100, A-564, G531 prosthetic sealants are intended to be used on patients who need a maxillofacial prosthesis due to the loss of facial parts due to congenital malformation, tumour surgery or trauma of the craniofacial region.

INDICATIONS OF USE:

A-100, A-564, G531 prosthetic sealants are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Only to be used for sealing extrinsic colours onto cured prostheses.

PRODUCT RANGE:

A-100	- Acetoxy Silicone Sealant
A-564	- Acetoxy Silicone Sealant
G531	- Acetoxy Silicone Sealant

STORAGE:

A-100, A-564, G531 Sealants are supplied non-sterile in plastic or aluminium tubes and it is recommended that they are stored in their original containers. It is recommended that they are stored at ambient temperature (between 15 and 30 degrees Celsius) and out of direct sunlight. Do not use if the packaging is open or has been damaged and do not use after the labelled expiry date.

PRECAUTIONS / RESIDUAL RISKS / SIDE EFFECTS:

- Only use pH neutral soaps/cleansers to clean prosthesis/skin - avoid using aggressive chloride-based cleaning solutions.

-This material is designed for external use only on unbroken healed skin.

DISPOSAL:

Disposal of the materials should follow local regulations and environmental requirements taking different contamination levels into account.

IMPORTANT INFORMATION

It is the User's responsibility to ensure the safety and efficacy of these materials for all intended uses. While the materials have been deemed safe for use as external prostheses on unbroken healed skin, Technovent makes no end use representation based on such testing. It must be understood that because conditions and methods of use of our products is beyond our control, the information in this document should not be used in substitution for customer's tests to ensure the product is safe, effective and fully satisfactory for the intended end use.

Designed for external use only.

HARMONISED SYMBOLS:



Consult Instructions for Use



Lot Number



Manufacturer



Product Code/Ref



Manufacturing Date



Do Not Store in Direct Sunlight



Expiry Date



Do Not Use if Packaging is Open/Damaged



Store Between 15-30 Degrees Celsius



Authorised Representative in the European Community



Medical Device