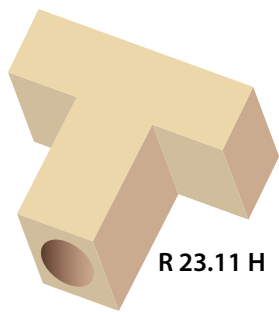
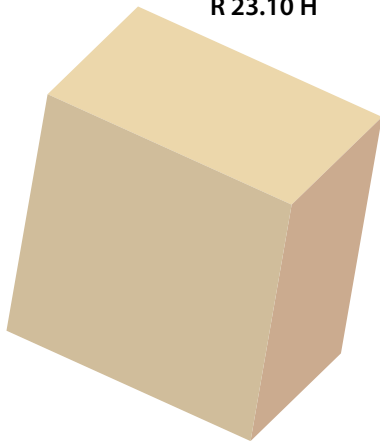
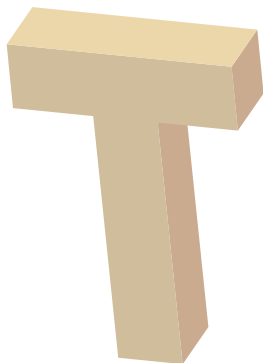


AUDIOBLANK

R 23.10 H



R 23.11 H



R 23.12 H

TREATED EQUINE CHONDROPROSTHESIS

The use of cartilage is becoming increasingly widespread in tympanoplasty for the reconstruction of the ossicular chain.

Cartilage of three different sources can be found: autologous, homologous or heterologous. The use of autologous cartilage entails a second surgery on the patient's nasal septum or the pinna, with relevant scar and extended surgical time.

Homologous cartilage must mandatorily come from a certified tissue bank, which entails considerable logistics and financial problems

AUDIOBLANK® heterologous cartilage, taken from the nasal septum of horses, features excellent bio-mechanical characteristics, moreover:

- it is ready to use: pre-formed in the classic total and partial forms or in carving blocks;
- it is safe as regards all the infections transmissible to humans;
- it affixes the CE marking from the Italian Institute of Health, hence the surgeon is safeguarded against any medico-legal disputes



audio®
TECHNOLOGIES

ORIGINS OF THE BIOMATERIAL

Studies on bovine cartilage revealed that it possessed many properties typical of human cartilage.

In 1985, Audio Technologies Laboratories began a series of trials with bovine, swine

and equine cartilage with a view to be able to use it as a substitute for human cartilage. Up to date, this product has been used in thousands of cases for the reconstruction of the floor of the orbit, of the external and middle ears, of the nasal septum, of the cranial wall and, more recently, in dental implantology.

In all fields this product has been widely acknowledged for the total absence of irritative phenomena.

AUDIOBLANK® can be fixed pushing it precisely towards the concerned area, e.g. the orbital fundus, or fixed through suture.

Before implanting AUDIOBLANK®, we suggest to dip it in antibiotic solution.

After opening the package, the remaining material cannot be neither used nor re-sterilized.

AUDIOBLANK® has already been used in oculistics, maxillofacial surgery, neurosurgery, rhinology, otology, plastic surgery and put in contact with nerves, bones, cartilaginous, muscular and cutaneous tissues with very good results.

AUDIOBLANK® surfaces are finely knurled thus increasing the surface-volume ratio and enabling a strong grip on the surrounding tissues to avoid prosthesis shifts.

The prosthesis becomes stable in about 6 weeks and it is surrounded by a fibrous capsule which can be easily removed in case of revisions.

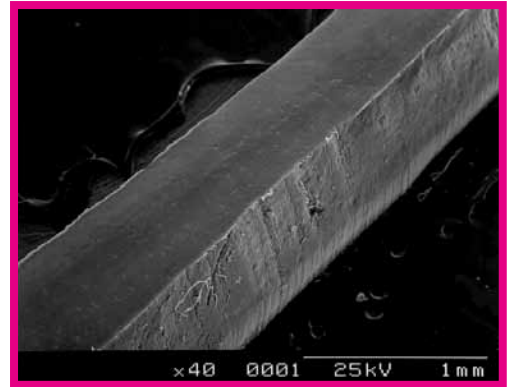
AUDIOBLANK® is accepted as a bioinert implantation, it may be partially reabsorbed. Possible infectious processes quicken the reabsorption.

AUDIOBLANK® can be left in its position even in case of infection: the wound recovers without need to remove the implant. AUDIOBLANK® shall not be applied to patients allergic to equine meat.

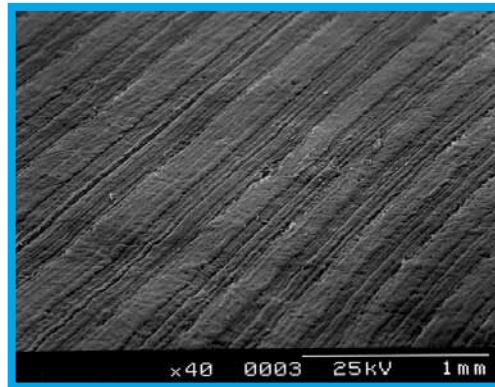
AUDIOBLANK® is packaged separately in a double envelope for β rays sterilization. The inner envelope contains propylene oxide solution: AUDIOBLANK® must be washed 3 times for 10 minutes in 50 cc. physiologic solution before use.

AUDIOBLANK

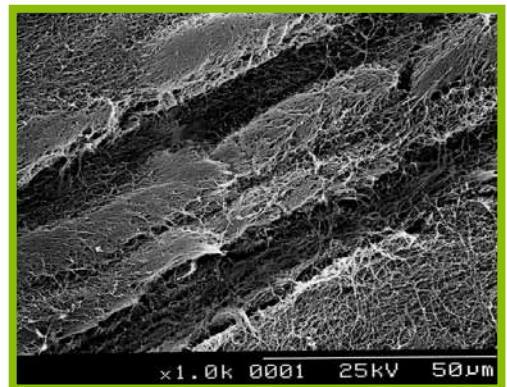
SEM image of the edge of the AUDIOBLANK® 500 microns thick. Edge of amorphous section, surface of the membrane delicately grooved.



SEM image of the surface of the AUDIOBLANK®. The furrowed appearance increases adhesion to coating tissues, thus favouring its early stabilization.



SEM image of the surface of the AUDIOBLANK®. Two microgrooves are visible. The apparently amorphous mass of the cartilage is made up of interlacing collagen fibres.

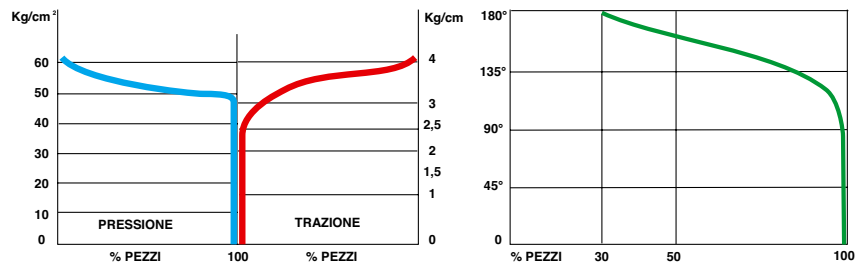


AUDIOBLANK

MECHANICAL RESISTANCE

AUDIOBLANK® resists to pressures of 50 kg./cm.2 and to traction of 2.5 kg. on a linear tract of 1 cm. It can be folded at right angles without splitting, so long as too much compression is not placed on the fold.

AUDIOBLANK® presents resistance to pressure and to traction greater than that required for surgical procedures. It is so flexible that the membrane can be folded at right angles so long as not too much compression is placed on the actual fold.



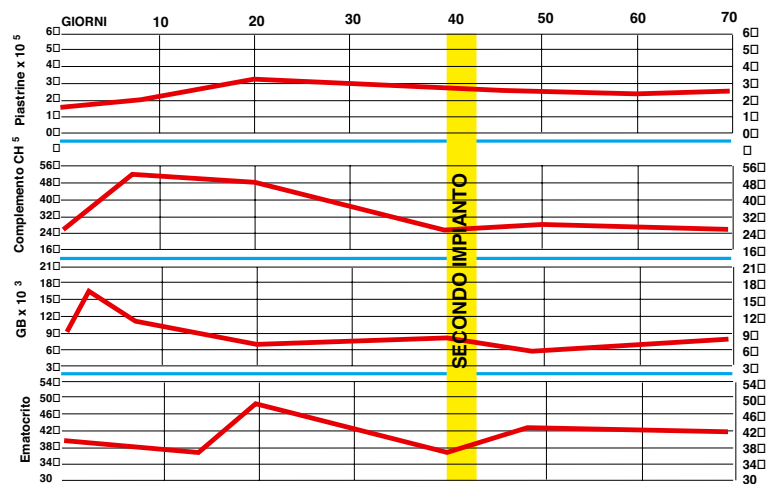
CLINICAL CHARACTERISTICS OF THE BIOMATERIAL

Experiments carried out on animals have shown that encapsulation takes place in the same way as for that of all inert foreign bodies.

Research has shown that problems linked to antigenicity do not exist; clinical studies have shown that the use of treated equine cartilage in man is harmless.

Tests for pyrogenicity and direct contact cytotoxicity, carried out on commercially packaged AUDIOBLANK® proved that the product was not pyrogenic and not cytotoxic: direct contact cytotoxicity grade zero.


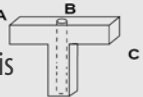
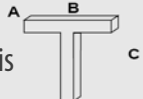
Results of a study which demonstrates that there are no significant changes in blood parameters after first implant with treated equine cartilage and after second implant (study of sensitivity). Neither the first nor the second implants induce an antigen-antibody response that can be systematically observed.



BIOINERTIA

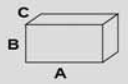
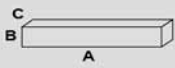
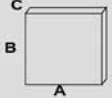



AUDIOBLANK® is a biomaterial treated and sterilized so that it can be tolerated by the human body in the same way as any inert implant. If infection takes place, it can be blocked with antibiotics; infection speeds up reabsorption times.

AUDIOBLANK formed grafts for tympanoplasty

	DIMENSIONS mm	DIMENSIONS mm			CODE
		A	B	C	
Block for tympanoplasty 		3	7	8	R 23.10 H
Partial chondroprosthesis 		3	5	6	R 23.11 H
Total chondroprosthesis 		1,8	5	8	R 23.12 H

Total and partial prostheses can be shortened using a surgical scalpel upon measuring (measuring instrument code TPL 02.14). The tip of the stem of the total prosthesis can be made thinner with the scalpel so as to adapt it to the dimensions of the footplate of the stapes.

AUDIOBLANK blocks and sheets of regular shapes

	DIMENSIONS mm	DIMENSIONS mm			CODE
		A	B	C	
Block 		35	25	4	R 23.01 H
Nasal block 		50	10	4	R 23.02 H
Sheet 		50	50	2	R 23.03 H
Orbital floor 			Ø 25	2	R 23.04 H
Ear block 		20	15	4	R 23.05 H
Chin block 		30	15	4	R 23.06 H

TREATED EQUINE CHONDROPROSTHESIS

AUDIOBLANK® is derived from equine cartilage, stripped of the perichondrium; the remaining structure is treated chemically and sterilized via radiation. Immediately after being removed, the cartilage is transferred to laboratories where the best parts for construction of the biomembrane are selected. The selected portions of cartilage are then treated chemically and examined under the operating microscope in order to select the areas which are more suitable for use on the grounds of consistency and elasticity; after which they are thinned down and cut into preformed shapes.

The surface of AUDIOBLANK® is modelled into microfurrows in order to increase the surface-volume ratio.

All above mentioned methods are in compliance with the ISO/CE norms which require monitoring of each phase of preparation, of the origin of lots of the cartilage, of the control cards for machinery used, of flow charts for production and of quality controls carried out with purpose-built equipment for checks on the intermediate and final products.

AUDIOBLANK®, at the end of the work cycle, is tested for flexibility and resistance. The treated sheets are dipped in a mixture of propylene oxide and ethyl alcohol for the preservation and sterilization. Processing and packing of AUDIOBLANK® is carried out in a white room with class "10000" filtered atmosphere, on laminar flow benches, in order to avoid air contamination. For each lot the microbiological enumeration is carried out when the work cycles have been completed in order to establish whether it is suitable for sterilization. If any batch at this stage exceeds a predetermined level of micro-organisms per gram, it is not admitted to the subsequent sterilization and packaging phases. Test for cytotoxicity and pyrogenicity carried out on the final product ready for distribution, showed that AUDIOBLANK® does not cause inflammatory processes of the tissue. AUDIOBLANK® is presented in double packets containing keeping solution for maintenance of the product. Each package exhibits data referred to sterilization, sell-by dates, lot number and product code.

CONTRAINDICATIONS

AUDIOBLANK® should not be implanted in patients with allergies to bovine meat.

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