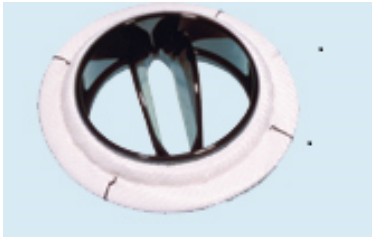
PRODUCTS OF MEDENG GROUP

CARDIOVASCULAR SURGERY



Mechanical prosthetic heart valve “CardiaMed”

The prosthetic heart valve “CardiaMed” was designed on the basis of clinical data derived from many generations of prosthetic heart valves. It embodies the most up-to-date scientific achievements, materials, and unique design patented in the USA, Europe and Russia. The findings of clinical studies have been repeatedly published and reported at the national and international conferences. The valve “CardiaMed” is available in various sizes from 17mm to 33mm with a step of 2mm. The valve is supplied sterile with a shelf life of 5 years.

Central-flow mechanical prosthetic heart valve “CardiaMed-CT”

One of its distinguishing features is the locking element formed in the shape of two cylindrical segments encompassing the blood flow from the outer side, which ensures natural flow structure in the heart cavities, reduces blood trauma to the minimum, increases effective orifice area and lowers pressure gradient across the prosthesis. The valve “CardiaMed-CT” is available in various sizes from 17mm to 33mm with a step of 2mm. The valve is supplied sterile with a shelf life of 5 years.

Biological prosthetic heart valve “CardiaMed-BIO”

It is used for replacement of diseased native heart valves which performance was irreversibly affected. Design of the sewing cuff has an unlocking element “Easy Change” that allows implanting the valve into the sewing cuff preliminary stitched to the patient tissue annulus. Stitching a sewing cuff without a valve mounted on it, facilitates access to intracardiac structures and allows removing anatomical defects before the valve is inserted.

ATTACHABLE PROSTHETIC HEART VALVE SEWING CUFF WITH SEAMLESS FIXATION.

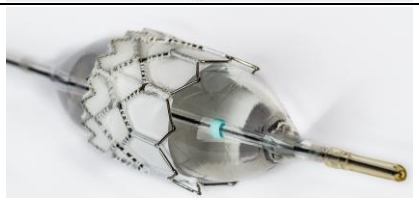
Explicit and user-friendly implantation technique reduces myocardial ischaemia time. Design of the sewing cuff has an unlocking element “Easy Change-Easy Fix” that allows implanting the valve into the sewing cuff preliminary stitched to the patient tissue annulus. Stitching a sewing cuff without a valve mounted on it, facilitates access to intracardiac structures and allows removing anatomical defects before the valve is inserted.

Ascending aortic prosthesis

It's a first domestic valved conduit which successfully combines the quality of the carbon open flow prosthetic heart valves "CardiaMed" and special technology of the vessel graft attachment which excludes bleedings. The prosthesis is available in various sizes from 21mm to 29mm

Transcatheter prosthetic heart valve "MEDLAB-KT" with transapical delivery system

It is intended **for transapical delivery** of a prosthetic heart valve in patients with severe symptomatic stenosis of an aortic valve when contraindications to an open heart surgery are present. The following modifications are available: an animal aortic prosthetic heart valve tissue (ALB), polymer aortic prosthetic heart valve (ALM). The leaflets of the polymer valve are made of ePTFE, of the tissue valve – of calf pericardium. The prosthesis is available in various sizes from 23mm to 27mm.

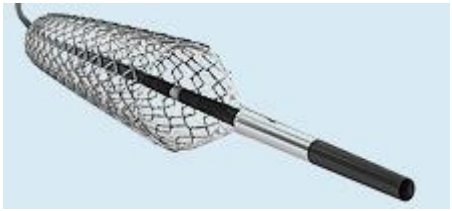


Transcatheter prosthetic heart valve "MEDLAB-KT" with transfemoral delivery system

"MEDLAB-KT" heart valve prosthesis with **transfemoral delivery system** for patients with severe symptomatic stenosis. The following modifications are available: an animal aortic prosthetic heart valve tissue (ALB), polymer aortic prosthetic heart valve (ALM). The leaflets of the polymer valve are made of ePTFE, of the tissue valve – of calf pericardium. The prosthesis is available in various sizes from 23mm to 27mm.

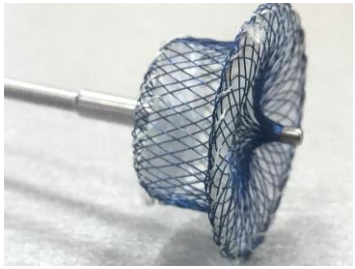
Annuloplasty rings "CardiaMed"

It's an optimal combination of elasticity, resilience, and usability. The rings are intended for treatment of mitral and aortic valve lesions. The ring material allows adapting its shape to the anatomical peculiarities caused, for example, by a heart attack. The rings are supplied in 10 modifications with sizes from 26 to 40. The rings are supplied sterile in a set with sizers and handles and have a 5-year shelf life.



Coronary stents

We offer a wide range of products for successful angiography and angioplasty procedures in coronary and peripheral arteries, including stents with a medicinal antiproliferative coating, with drug-eluting and carbon coating, with bioinert carbon coating and bare metal stents. The specific design and material features, radial resistance, ensure excellent delivering capability in conditions of a complex anatomy. It ensures uniform support to the vessel wall, guarantees biocompatibility and even drug release. The quality and performance of the product is demonstrated over a long period and is superior to similar imported devices.

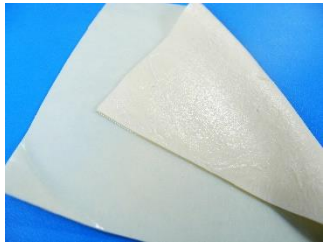


Cardiological occluder

The cardiological occluder "NanoMed" is designed to perform endovascular closure of congenital and acquired heart defects such as atrial septal defect, ventricular septal defect and open arterial duct.. The occluder is a self-rotating, occlusive device made of nitinol wire mesh. A polyester fiber membrane is located inside the occluder frame.

The delivery system is designed for endovascular implantation of an occluder for the
elimination of congenital heart defects, such as atrial septal defect, ventricular septal defect and open ductus arteriosus. The delivery system is available in various versions with ending angle 45 ° (Sizes 5F, 6F, 7F, 8F, 9F, 10F, 12F, 14F).

Xenopericardial patch “Cardioplant”

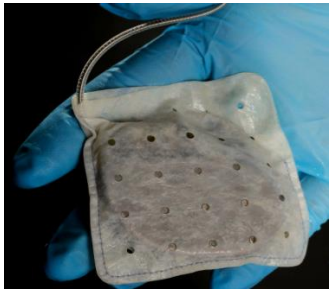


Patch based on decellularized highly purified pet pericardium for plasty of intra and pericardial tissues. The raw material for manufacturing the product undergoes a complex multi-stage chemical and biological processing according to a patented technology using anti-calcium matrix-saving techniques. Due to this all carriers of antigenicity - cellular elements and glycosaminoglycans of the intercellular matrix are completely removed from the biotissue. The structural architectonics of fibrillar proteins remains intact. This allows the patch to act as a matrix for colonizing recipient cells, transform into its own healthy tissues and metabolize according to the laws of natural processes. The patch is absolutely biologically-compatible. The patented technology of anti-calcium treatment prevents the formation of insoluble deposits of calcium salts by screening. During 11 years of using the product in more than 80 clinics, no cases of calcification of the product were detected. It has a two layer structure –a smooth resistant side and a woolly, capable for active integration. It is supplied in a specially developed preservative solution that does not require long term washing. For convenience the delivery set includes sterile accessories — a washing container and a disposable tweezer.

The single-cusp xenotransplantat “Cardioplant”

The product is intended for reconstruction of the right ventricle and pulmonary artery trunk. The product is made of two patches sewn in a certain way on the basis of decellularized non-immunogenic biologically-compatible xenopericardial tissue of the calf. It consists of a base and a locking element that follows the shape of a natural cusp. The thickness of the locking element is uniform and does not exceed 0.5 mm; the thickness of the base can be from 0.3 to 0.7 mm. The design of the locking element prevents the formation of stagnant zones and gives the product excellent hemodynamic characteristics. It is delivered in a specially developed proprietary preservative environment. The duration of preoperative preparation (washing) in a sterile saline solution is 4 minutes. It is possible to manufacture six standard sizes of the product.

Biological envelope for cied «bioNEST» “Cardioplant”

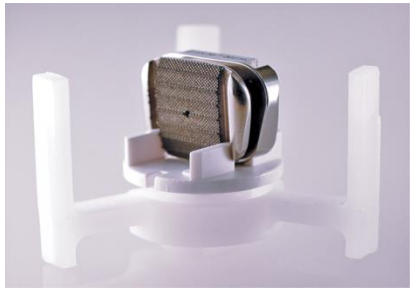


The product is intended to be used with implantable electronic devices (CIED) prior to implantation. The porous structure of the sheath material makes it possible to impregnate the product with solutions of drugs (for example, antibiotics) before implantation, reducing the risk of developing an infectious complication after surgery. The device is securely held under the skin without the risk of migration, pressure sores or fistulas. The hemostatic properties of natural collagen are complemented by the effective action of aminocaproic acid impregnated into the product. The active components contained in the material stimulate the processes of vascularization and biointegration, contributing to the formation of healthy surrounding tissues without adhesions to the electrodes, facilitating reimplantation.

Protector for mini-invasive operations

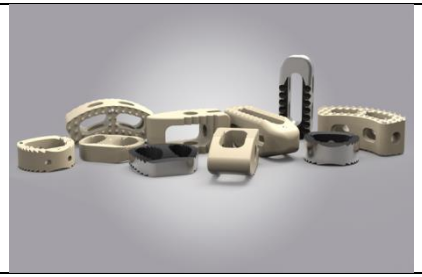
It’s a sterile medical device intended for providing access to the sternal cavity in mini-invasive operations. The protector is made of two rings connected by a silicone membrane. The available diameters are 40 and 60mm.

NEUROSURGERY, TRAUMATOLOGY AND ORTHOPAEDICS



Dynamic intervertebral disk endoprosthesis “ENDOCARBON”

Dynamic intervertebral disk endoprosthesis “Endocarbon” is intended to replace defective or pathologically changed native disks at degenerative-dystrophic damages and prosthesis in cervical spine pathology. The device is used for implantation at the levels from C3 to C7. The endoprosthesis restores the height and functional mobility of the operated segment of the intervertebral disc. The design provides vertebral mobility in accordance with natural, physiological mobility.

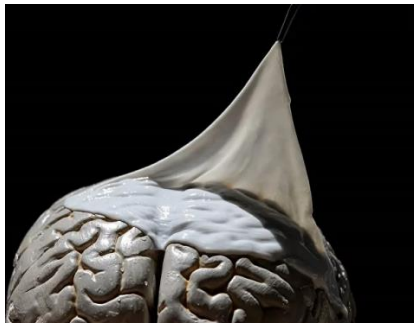


Interbody fusion cages “ENDO”

“Endo” is a set of cages for interbody spinal fusion. The set consist of different sizes cages made of titanium and Peek-polymer that are implanting into the area between vertebral bodies of different regions of the vertebral column to support and correction of vertebrae’s location after surgical intervention aimed at interbody fusion formation.

Total elbow endoprosthesis "ENDOCARBON"

Designed to replace a damaged or pathologically altered elbow joint in degenerative-dystrophic injuries. In operations for prosthetics of elbow joint pathologies. Total elbow endoprosthesis "ENDOCARBON" is a modular construction which allows combining the shoulder and elbow components of different sizes for a better anatomic fit. Anterior flange (projection) provides secure rotational stability of the humeral stem. Assembly of the endoprosthesis is achieved by a fixture in the tube to reliably anchor the humeral and ulnar components. Feet of endoprosthesis have double microscopic surface elaboration providing the best endoprosthesis fixation in a bone that accelerates osseointegration processes.



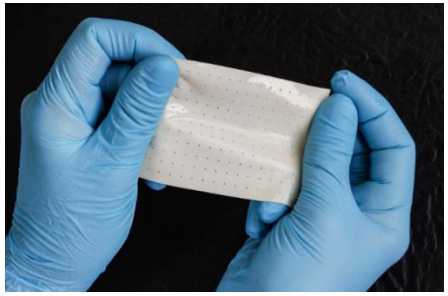
Biological prosthesis of dura mater "XENODURA"

It´s a natural collagen prosthesis that is equivalent to the human dura mater. The product is a highly purified biological matrix based on collagen and elastin of xenogenic origin. The matrix acts as a tissue-engineering scaffold for fast migration, colonization with the patient’s own cells and physiological regeneration of the dura mater. The prosthesis “xenoDURA” is indicated for repairing of the dural defects, secure sealing with subsequent replacement with the patient’s own tissue. The product consists of highly purified raw materials of animal origin that have passed strict veterinary control. The safety and efficacy of the prosthesis have been confirmed by numerous preclinical tests and clinical trials. The manufacturing process includes a patented stage of deep physiological purification through supercritical fluid extraction. The “smart” processing makes it possible to obtain a matrix with preserved native structure of architectonic proteins, that is maximally free from cells and immunogenic agents. We do not use any toxic cross-linking agents in the manufacturing process. The product undergoes bioresorption and involves into the metabolism in line with the natural laws, gradually being replaced by the patient’s own dura mater. In addition, a special treatment of the raw material prevents any damage to the collagen fibers of the dense native serous layer, and its adhesion with the brain.

Natural bone graft for neurosurgery "BIO-OST"

Osteoplastic matrix in the form of granules of different sizes and volumes. Natural osteoplastic material. A mixture based on spongy and cortical bone tissue with collagen to fill in bone defects of vertebral bodies. Small granules are designed to fill small defects, complex narrow areas or to fill large defects in combination with other materials. Medium-sized granules are mainly used for filling medium and large cavities. After implantation a bimodal porous structure is formed (an open porous structure with a pore size of 200-500 μm for sprouting into the material of bone cells and vessels and micropores less than 100 μm for interstitial body fluids) of bone tissue. The rate of resorption depends on the properties of the patient's receiving bed and can range from 6 to 16 months, which corresponds to the rate of physiological replacement of the defect. The size of granules from 1 to 4 mm allows to fill defects of complex shape as effectively as possible, because smaller granules are able to fill all complex terrain areas, providing maximum contact with the recipient's bone, and larger granules maintain the necessary volume of the matrix. In addition the combination of spongy bone granules with cortical, which has a different rate of resorption, allows for good angiogenesis. Graft after implantation retains the necessary strength and volume, later being rebuilt into bone tissue. This eliminates the "shrinkage" of the regenerate. The matrix in the form of granules consists of separate fractions of the spongy and cortical layer of bone, which provides both a pronounced osteoconductive effect and background osteoinductive properties. The presence of cortical granules in the product ensures long term preservation of volume and seals the defect.

Surgical implant "CARDIOPLANT"

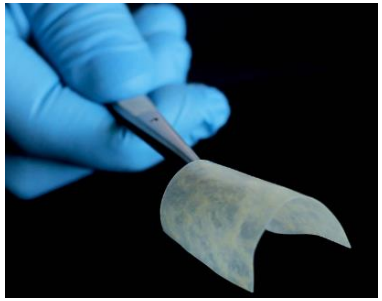


Sterile absorbable sheet 3-D biological material with a wide range of applications for the replacement of affected areas of defects in organs and tissues in various parts of the body. It is used as a framework for soft tissue regeneration. The implant is made of a pericardial bag of xenogenic origin. It is a highly purified cell-free collagen elastic biopolymer, antigen-neutral, resistant to infection, and has a growth potential. The implant is made from animal tissues using a patented technology using decellularizing matrix-saving technologies. After implantation, it is populated with cells, vascularized and transformed by natural metabolism into its own tissues without the formation of scars and adhesions. Thanks to the "cross-link" processing technology the implant is resistant to tissue and bacterial enzymes, so the process of resorption proceeds slower than the process of formation of new healthy tissue. This behavior ensures permanent and reliable strengthening of soft tissues. The time of resorption depends on the thickness of the implant and the receiving substrate and is from 4 to 12 months. It is an excellent alternative to the use of synthetic materials (for example, non-absorbable polymer meshes that eventually form a rough scar tissue). Implant can be perforated or not. Implant can be used for sleeve gastroplasty in bariatric surgery.

Osteoplastic material for orthopedics “BIO-OST“

Natural bone substitute with a bimodal porous structure with different fragmentation and different behavior to solve any clinical problem. It is used in traumatology and orthopedics to fill in bone defects, treat of delayed consolidation, false joints and other reconstructive operations. The "Bio-Ost" matrix is a purified sterile bone tissue of young cattle that has passed strict veterinary control. Depending on the residual content of the inorganic phase, the osteoplastic matrix is produced demineralized (with a reduced mineral content) and non-demineralized. During demineralization native bone growth factor proteins sewn with hydroxyapatite open, which provides background osteoinducing properties of the matrix. As a result the mineral-collagen matrix demonstrates both osteoconductive and osteoinductive properties, which allows us to achieve the highest quality results when replacing bone defects. Non-mineralized matrix has osteoconductive properties and high enough strength. When used as an osteoplastic material, it allows you to form the necessary volume of bone regenerate. The bone matrix of different fragmentation and different behavior can solve any clinical problem.

«CHONDRO-SCAFFOLD» membrane



Collagen matrix for induction of chondrogenesis. The Chondro-SCAFFOLD membrane is a unique development in the line of products for traumatology. This high-tech product has no analogues on the Russian market and was developed under the guidance of leading experts. The membrane is a matrix or scaffold based on extracellular collagen matrix of the submucosal base of the pig's small intestine (SIS-small intestine submucosa). It contains type I and III collagen, elastin, glycosaminoglycans (heparin, chondroitin sulfate A) and proteoglycans (decorin, heparin-sulfate), which provide active adhesion, cell proliferation, migration and binding, regulation of the fibrillar structure of proteins and active angiogenesis. Due to the presence of residual decorin, it does not form scars and adhesions, after implantation it is "populated by cells" of the surrounding tissue, and very quickly transforms into cartilage tissue.The membrane is intended for use in orthopedics in order to regenerate damaged articular cartilage using the "StaMP" method (directed autochondrogenesis on an extracellular scaffold). The use of the membrane helps to reduce pain in the postoperative period, faster and more effective recovery of cartilage tissue. The safety and effectiveness of the medical device has been proven.

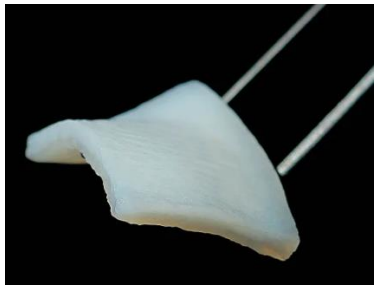
DENTISTRY AND MAXILLOFACIAL SURGERY

Dental bone graft

Depending on the residual content of the inorganic phase, the bioOST bone matrix is produced with or without collagen. During demineralization bone growth factor proteins sewn with hydroxyapatite are opened. This provides the osteoinducing properties of the matrix. The mineral-collagen matrix demonstrates both osteoconductive and background osteoinductive properties, which allows to achieve the highest quality results. The heat-treated material does not contain collagen. This matrix is a ceramized hydroxyapatite of animal origin (granules of biological apatite and amorphous calcium phosphate in the "natural ratio"). This material has osteoconductive properties and high enough strength. It allows to form the necessary volume of bone regenerate. The material is produced in the form of granules of different sizes, blocks and plates.

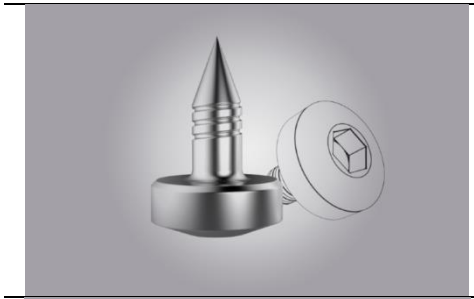
Collagen dental membranes

BioPLATE series membranes are represented by two products. The classic two-layer bioresorbable barrier membrane bioPLATE Barrier, necessary for sinus lifting, GTR therapy — has excellent physical and mechanical properties and reliably provides a barrier function. The second product - bioPLATE Contur — has similar biological and barrier properties, but it is characterized by high indicators of stretchability and elasticity. The product is designed for more convenient performance of "pulling" techniques.



Dental collagen 3d-matrix «FIBROMATRIX»

FibroMATRIX is a volumetric collagen biomaterial. Designed specifically for soft tissue regeneration. The patented raw material processing technology allows to get a dense and volumetric matrix that provides a stable volume without shrinkage. After implantation, biointegration and transformation into healthy tissue occurs quickly with early vascularization of the regenerate. The regenerate has a good aesthetic color and texture after healing. Due to its strength, unlike similar products, it does not erupt through the thread during modeling. Stable volume s upporting 3D collagen matrix is used to increase the area and volume of soft tissue around natural teeth and implants. It is easily modeled in size and thickness using a scalpel (in the dry state) and scissors (in the wet state). It is fixed by means of seams, allows open conducting. FibroMATRIX is an excellent alternative to autogenous connective tissue transplant. An indispensable assistant to the surgeon in restoring the "pink aesthetics".

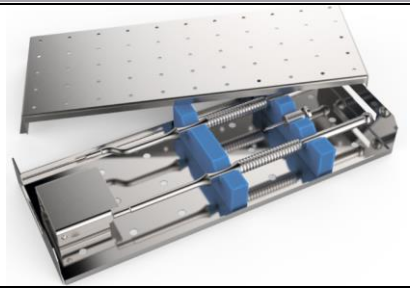


Pins for fixing membranes

They are a hybrid between a screw and a pin. The versatile design allows the use of pins in any, even the most difficult clinical situation. The thread on the stem ensures a better anchoring of the pin in the bone and its easy removal after the regeneration period. The sharp tip and heavy-duty pin allow insertion of the pin into the bone of any bone density. The pins are made of titanium alloy, which makes them fully biocompatible.

Screws for fixing membranes

The screws are designed for stable fixation of resorbable and nonresorbable membranes as well as titanium meshes. The heads of the screws have a Phillips head slot, which provides the most rigid fixation of the screw on the crewdriver blade. The design of the screws and screwdrivers provides a good friction fit. During screw insertion, the screwdriver blade is firmly connected to the screw head.



Sterilisation box

	**Casette for sterilization of pins**
	**Bent pin holder, straight**
	**Surgical hammer**
	**Pin holder, straight**

MedEng