COMPARATIVE ANALYSIS OF METALLIC ENDOVASCULAR COIL FRAME DESIGNS

Chepeleva EV[1] ✉, Kozyr KV[1], Borodin VP[1], Khakhalkin VV[1], Vladimirov SV[1], Makhmudov MA[1], Badoian AG[1], Baranov AA[1], Krestyaninov OV[1,2]

[1] Meshalkin National Medical Research Center, Novosibirsk, Russia
[2] Novosibirsk State Medical University, Novosibirsk, Russia

Currently the development of the production of domestic medical devices is of special importance in the context of ensuring the healthcare system sustainability. Leveraging international experience in developing embolic coils, while considering the capabilities of Russian production, will enable the creation of devices that meet global standarts. The study aimed to conduct systematic evaluation of six endovascular coil models from leading foreign manufacturers and perform comprehensive assessment of the design features of the metal coil frames, including analysis of geometrical dimensions, materials used, and engineering solutions. Based on our findings and a comparison with clinical and experimental literature data we determined the optimal parameters for creating the coil prototype: the wire diameter 0.07–0.12 mm, coil-core type interlock mechanism, and atraumatic polymer tip. These solutions ensure the optimal combination of performance characteristics and manufacturability. The findings provide the basis for the development of domestic analogues meeting the today's clinical requirements, considering the available production capacity.

Keywords: endovascular coils, vascular embolization, vascular surgery, shape memory materials, production technologies

Funding: the study was conducted as part of the Russian Science Foundation project No. 25-15-00480.

Author contribution: Chepeleva EV — data analysis, manuscript writing and editing; Kozyr KV, Borodin VP — experimental procedure, data analysis, visualization of findings; Khakhalkin VV — study concept and design, data analysis; Vladimirov SV — experimental procedure, data analysis, visualization of findings; Makhmudov MA, Badoian AG, Baranov AA — technical support, data validation, graphics design; Krestyaninov OV — general research management, coordinating work, editing and approval of the final version of the manuscript.

✉ **Correspondence should be addressed:** Elena V. Chepeleva
Rechkunovskaya, 15, Novosibirsk, 630055, Russia; e_chepeleva@meshalkin.ru

Received: 15.09.2025 **Accepted:** 30.09.2025 **Published online:** 23.10.2025

DOI: 10.24075/brsmu.2025.048

СРАВНИТЕЛЬНЫЙ АНАЛИЗ КОНСТРУКЦИЙ МЕТАЛЛИЧЕСКИХ КАРКАСОВ ЭНДОВАСКУЛЯРНЫХ СПИРАЛЕЙ

Е. В. Чепелева[1] ✉, К. В. Козырь[1], В. П. Бородин[1], В. В. Хахалкин[1], С. В. Владимиров[1], М. А. Махмудов[1], А. Г. Бадоян[1], А. А. Баранов[1], О. В. Крестьянинов[1,2]

[1] Национальный медицинский исследовательский центр имени Е. Н. Мешалкина, Новосибирск, Россия
[2] Новосибирский государственный медицинский университет, Новосибирск, Россия

В современных условиях развитие отечественного производства медицинских изделий приобретает особое значение в контексте обеспечения устойчивости системы здравоохранения. Использование международного опыта при разработке эмболизационных спиралей с учетом возможностей российских производств позволит создать изделия, соответствующие мировым стандартам. Целью работы было провести систематический анализ шести моделей эндоваскулярных спиралей ведущих зарубежных производителей и комплексное изучение конструктивных особенностей металлических каркасов спирали, включая оценку геометрических параметров, используемых материалов и технических решений. По результатам исследования и их сопоставления с клиническими и экспериментальными литературными данными определены оптимальные параметры для создания прототипа спирали: диаметр проволоки 0,07–0,12 мм, замковый механизм типа «спираль-сердечник» и полимерный атравматический кончик. Данные решения обеспечивают оптимальное сочетание эксплуатационных характеристик и технологичности изготовления. Полученные результаты формируют основу для разработки отечественных аналогов, соответствующих современным клиническим требованиям, с учетом имеющихся производственных возможностей.

Ключевые слова: эндоваскулярные спирали, эмболизация сосудов, сосудистая хирургия, материалы с памятью формы, технологии производства

Финансирование: исследование выполнено в рамках проекта Российского Научного Фонда № 25-15-00480.

Вклад авторов: Е. В. Чепелева — анализ данных, написание и редактирование текста статьи; К. В. Козырь, В. П. Бородин — проведение экспериментов, анализ данных, визуализация результатов; В. В. Хахалкин — концепция и дизайн исследования, анализ данных; С. В. Владимиров — проведение экспериментов, анализ данных, визуализация результатов; М. А. Махмудов, А. Г. Бадоян, А. А. Баранов — техническая поддержка, валидация данных, подготовка графических материалов; О. В. Крестьянинов — общее руководство исследованием, координация работы, редактирование и утверждение финальной версии текста.

✉ **Для корреспонденции:** Елена Васильевна Чепелева
ул. Речкуновская, д. 15, г. Новосибирск, 630055, Россия; e_chepeleva@meshalkin.ru

Статья получена: 15.09.2025 **Статья принята к печати:** 30.09.2025 **Опубликована онлайн:** 23.10.2025

DOI: 10.24075/vrgmu.2025.048

The dependence on imported endovascular coils for embolization is a major challenge for the public health system of the Russian Federation. Hundreds of thousands embolization surgical procedures due to vascular disorders are performed annually all over the world, and all the products used for this purpose in Russia are manufactured by foreign companies. In 2020, global sales of coils were about 1.14 billion of US dollars, in 2021 these reached 1.175 billion of US dollars, and the rate still demonstrates a steady upward trend [1]. Under conditions of import dependence there is a need for import substitution, and the analysis of world experience should be conducted to create versatile structures with optimal biotech properties.

Despite their common function, endovascular coils for vascular embolization vary considerably according to materials, geometry, and dimensions, but any coil represents a metal frame maid of the wire twisted into a primary coil [2]. The key requirements for the coils are as follows: high biocompatibility, controlled thrombogenicity, optimal radial stiffness and flexibility, as well as the ability to restore the 3D structure after implantation [3]. Polymer fibers or a hydrogel coating are often applied to the surface in order to enhance thrombogenicity, and the secondary coil configuration varies depending on the target blood vessel anatomy [4, 5]. The coils cause irreversible embolization, ensuring complete blood vessel occlusion due to thrombus formation [6]. Such an effect is achieved in one of three ways: mechanical obturation of the blood vessel lumen resulting in the considerably reduced blood flow; development of a thrombogenic frame contributing to platelet aggregation and stable blood clot formation; controlled damage to the blood vessel wall stimulating the release of endogenous procoagulant factors. Thrombotic occlusion usually occurs within five minutes after installation, despite the fact that temporal parameters may vary depending on the device type, blood vessel diameter, and baseline hemodynamics in the area embolized [6, 7].

Modern research in the field of vascular embolization demonstrates considerable progress in coil development, especially in the context of improving the materials and technologies for production of those. The key materials to produce endovascular coils include platinum alloys, nickel titanium (nitinol), stainless steel, and the magnesium and zinc-based biodegradable alloys [2, 8]. Despite high cost, platinum alloys are widely used in clinical practice due to exceptional radiopacity ensuring accurate imaging during the intervention, optimal flexibility making it possible to adapt to the complex blood vessel anatomy, and high biocompatibility minimizing the risk of immune reactions [9]. Nitinol possessing superelasticity and shape memory effect makes it possible to restore initial configuration of the coil after delivery, which is especially important when treating complex aneurysms [10]. The stainless steel coils show radiopacity, but are inferior to other alloys (for example, to platinum ones). Stiffness of those resulting from high strength can hamper tight installation into the blood vessel. Therefore, the stainless steel coils are used mostly for occlusion of large diameter blood vessels [11, 12]. Biodegradable alloys represent a promising avenue in endovascular technology. Their capability of the controlled resorption after performing the therapeutic function makes it possible to minimize the risk of delayed complications and avoid re-interventions. Furthermore, ensuring safety via monitoring the magnesium and zinc ion levels in biological tissues remains an important aspect of the use of such materials [13].

In parallel with the research in the field of materials science, the endovascular coil evolution is related to optimization of the coil structural parameters. Modifications of the recent years were focused on improving the detachment mechanisms, increasing the coil length (up to 50–60 cm), introducing flexible materials and innovative coatings that enhance thrombogenesis. The diverse morphology of the next-generation devices covers the spectrum between classic 2D configurations and 3D structures topographically adapted to the aneurysmal sac anatomy [4]. Introduction of nanocoatings (Target Nano, Axium EX) and 3D-printed constructs (Target 3D, Micrusframe) ensures effective filling of both small complex aneurisms and large cavities. Special focus is on biocompatible coatings: polyglycolic/polylactic acid microfilaments and hydrophilic acrylic copolymers, which minimize inflammatory responses [14–16]. It is assumed that the combination of additive technologies with bioactive coatings will make it possible to personalize selection of coiling systems considering the aneurism size, localization, and morphology, thereby increasing the endovascular intervention safety and efficacy.

The development of domestic endovascular coils requires a complex approach based on the analysis of relevant advances in materials science and engineering solutions. It is important to adapt world experience considering the specifics of the national industrial infrastructure and regulatory framework. This enables creation of competitive medical technologies compliant with international standards and meeting the demands of the domestic public health system. The systematic review of the key parameters of modern foreign endovascular coils, i.e. geometry, materials, frame features, and production technologies, will make it possible to identify the model design solutions typical for different manufacturers. It is assumed that comparison will reveal the dominant trends in the product key element design and make it possible to classify the coils based on the technological and structural characteristics. Understanding the relationship between materials, geometry, and production technologies will provide the basis for shaping the new criteria relevant for the development of innovative devices.

The study aimed to assess the dimensions, materials, and structural features of metal frames of the endovascular coils available on the market. The research objectives were as follows:

To conduct a systematic review of the range of endovascular coils in terms of geometric parameters (diameter, length, shape).

To perform microscopic analysis of the structural elements of the metal coil frames.

To characterize the methods to produce the key coil frame elements (atraumatic tip, main part and interlock).

To investigate the feature of the polymeric fiber attachment inside the frame and the effect of polymeric fibers on the structure.

METHODS

The following endovascular coils were studied:

1. Manufacturer COOK MEDICAL LLC (USA), model Nester G52754.
2. Manufacturer COOK MEDICAL LLC (USA), model MReye Flipper G20235.
3. Manufacturer MicroVention, Inc (USA), model Terumo AZUR 18 45-480810.
4. Manufacturer Boston Scientific Corporation (USA), model Interlock Spiral 2D M00136155.
5. Manufacturer Boston Scientific Corporation (USA), model Interlock Spiral -35 M001363700.
6. Manufacturer PFM Medical GmbH (Germany), model Nit-Occlud PDA 145044V1.

The coil dimensions and design features were assessed using the NORGAU NVMIII-2010D video measuring system (Norgau Russland LLC, Russia).

Table. Endovascular coil characteristics. Values are presented as M ± SD, where M is the mean; SD is the standard deviation; the 95% confidence interval for each mean is provided in parentheses.

Mnufacturer	Model	Coil wire material	Wire diameter, mm	Coil diameter, mm	Atraumatic tip type	Interlock mechanism type	Polymer fiber attachment
COOK MEDICAL LLC (USA)	Nester G52754	Platinum	0.125 ± 0.003 (0.116–0.134)	0.537 ± 0.004 (0.526–0.548)	Spherical, melted	Coil-coil (screw-type connection)	Between the coil turns due to friction
COOK MEDICAL LLC (USA)	MReye Flipper G20235	Inconel®	0.172 ± 0.003 (0.163–0.181)	0.777 ± 0.007 (0.760–0.794)	Spherical, brazed	Coil-coil (screw-type connection)	Between the coil t urns due to friction
MicroVention, Inc (USA)	Terumo AZUR 18 45-480810	Platinum	0.072 ± 0.005 (0.059–0.085)	0.302 ± 0.004 (0.291–0.313)	Nibbled, covered with polymer glue	Detachment by electrical current	Hydrophilic polymer in the form of a sheath
Boston Scientific Corporation (USA)	Interlock Spiral 2D M00136155	Platinum	0.079 ± 0.003 (0.070–0.088)	0.306 ± 0.004 (0.295–0.317)	Spherical, brazed	Milled interlock	Between the coil turns due to friction
Boston Scientific Corporation (USA)	Interlock Spiral -35 M001363700	Platinum	0.176 ± 0.005 (0.163–0.189)	0.526 ± 0.005 (0.513–0.539)	Spherical, brazed (the diameter is larger than the coil thickness)	Groove-groove milled interlock	Between the coil turns due to friction
PFM Medical GmbH	Nit-Occlud PDA 145044V1	Titanium nickelide	0.243 ± 0.003 (0.234–0.252)	0.763 ± 0.005 (0.750–0.776)	Spherical, brazed	Coil-core (semi-helicoidal connection)	No

The coil samples were positioned freely on the microscope stage without applying mechanical tension in order to avoid deformation. To ensure the contrast and measurement accuracy, we used the annular reflection light source allowing for clearly visualize the contours of the structural elements. Measurement was performed using the INSPEC software (Micro-Vu, USA). The procedure included manual selection of the contour with the subsequent use of the Distance tool to determine the key geometric parameters: external coil diameter (based on the spiral extreme points) and wire thickness (three measurement repeats per parameter). Statistical processing of the results was performed using the Student's t-test in Statistica 10.0 (StatSoft, USA). The data provided in the Table are presented as M ± SD, where M is the mean; SD is the standard deviation.

RESULTS

In terms of structure all the studied coils represent the spirals made of wire 0.07–0.25 mm in diameter (Table).

The Nester G52754 coil (COOK MEDICAL LLC) (Fig. 1) made of platinum consists of three elements: the atraumatic tip, the main coil with an increment equivalent to the wire diameter, and the interlock part. The interlock is achieved through screwing the spiral of the proximal coil part (about 2.2 mm long) onto the distal part of the delivery system. The

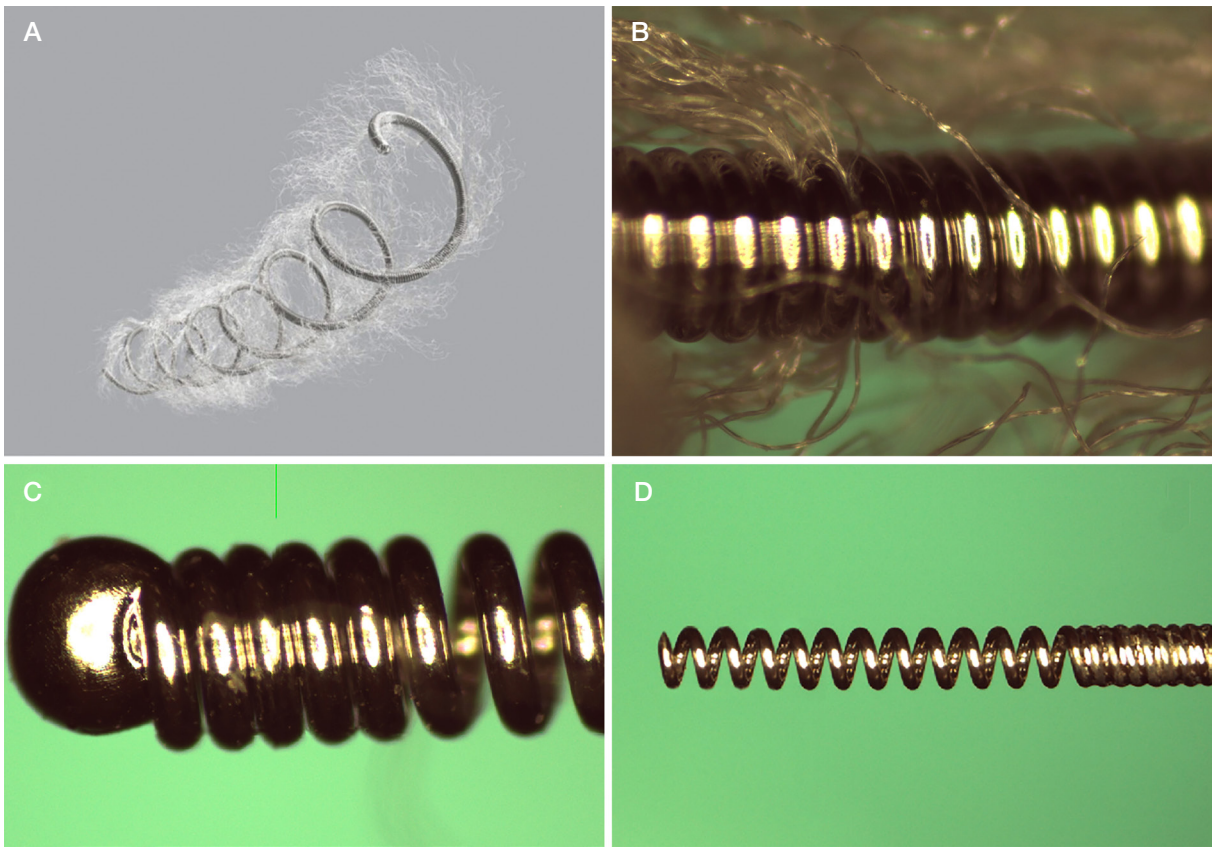

Fig. 1. Nester endovascular coil manufactured by COOK MEDICAL LLC: general view **(A)**; fiber attachment **(B)**; atraumatic tip **(C)**; interlock part **(D)**

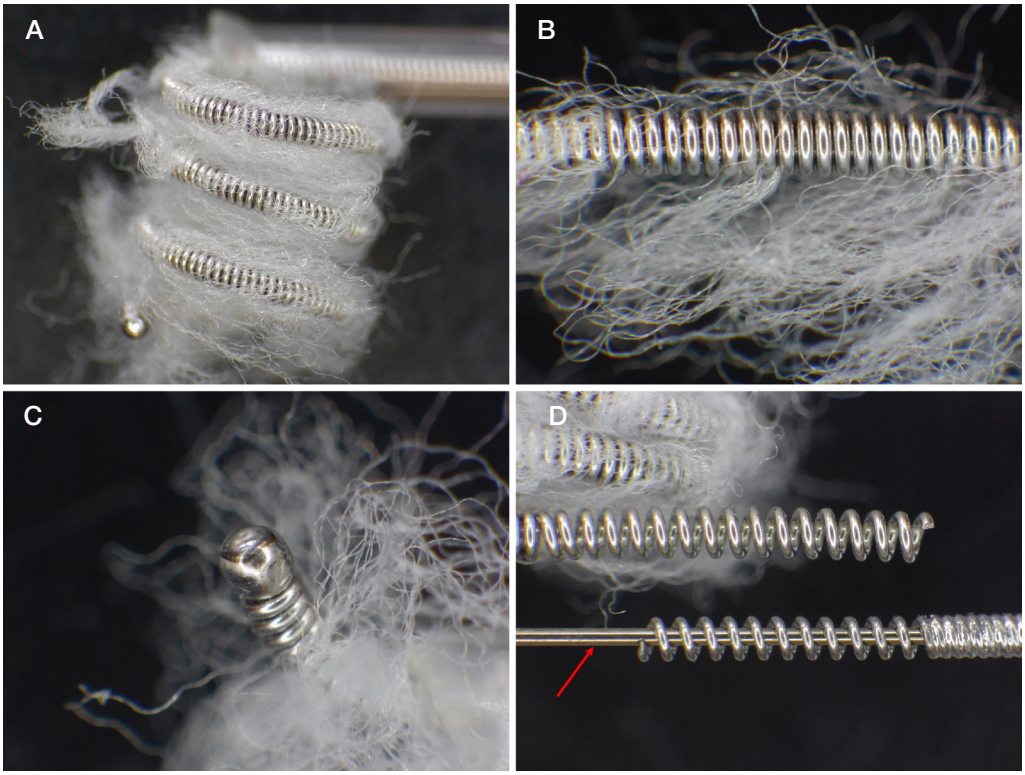

Fig. 2. MReye Flipper endovascular coil manufactured by COOK MEDICAL LLC: general view **(A)**; fiber attachment **(B)**; atraumatic tip **(C)**; interlock parts of the coil and delivery system, delivery system rod (red arrow) **(D)**

atraumatic tip is shaped by the reflow method. The interlock coil is attached to the main one by brazing. The polymer fibers are held between the spirals by friction.

The MReye Flipper G20235 coil (COOK MEDICAL LLC) (Fig. 2) is structurally similar to Nester, but made of the Inconel® alloy belonging to the family of the nickel-chromium heat-resistant alloys. Besides the material, the coil differs from Nester in geometric dimensions, it is also made of the larger diameter wire.

The Terumo AZUR 18 45-480810 coil (MicroVention, Inc.) (Fig. 3) belonging to the hydrogel coil family is made of platinum, the atraumatic tip is made of a polymer, and the main structural feature of the product is the Electric Detachment System (EDS) for smooth and predictable detachment of the coil from the delivery system. For realization of the EDS, the delivery system comprising two electrical conductors running throughout is connected to the handle (not presented in the figure) having a built-in galvanic power source and an activation button. After pushing the button the electrolysis process is launched, through which the low-voltage electric current dissolves the interlock pin in about 20 s, releasing the coil.

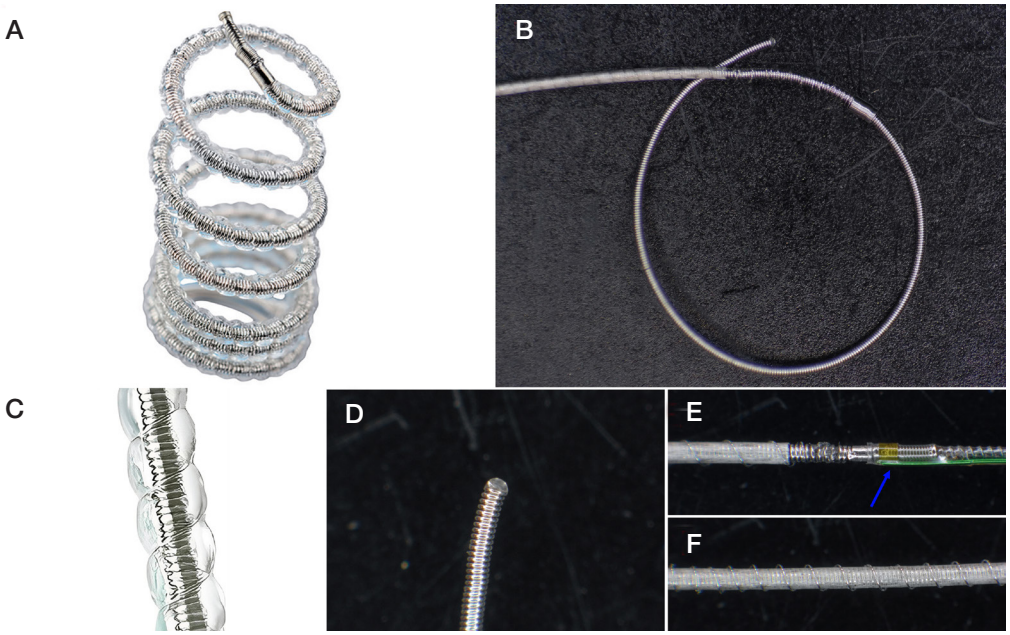

Fig. 3. Terumo AZUR 18 endovascular coil manufactured by MicroVention, Inc.: general view **(A)**; distal part of the coil, in which the margin, where the hydrogel sheath begins, is pointed with the red arrow **(B)**; activated hydrogel sheath **(C)**; atraumatic tip **(D)**; thermoelectric coil detachment system (blue *) **(E)**; hydrogel sheath **(F)**

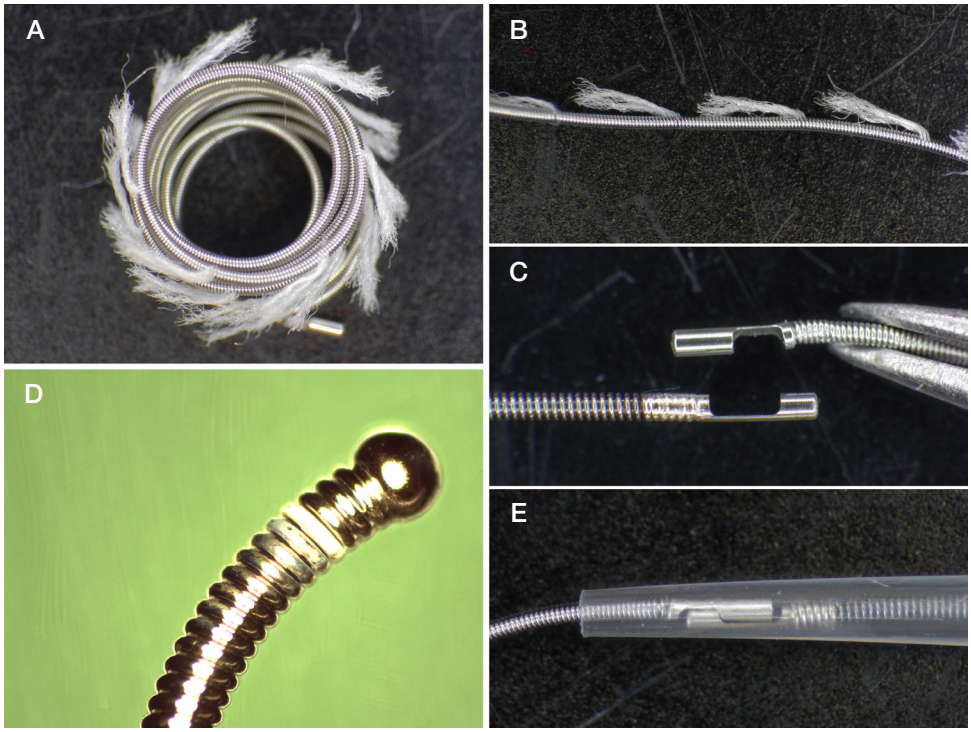

Fig. 4. Interlock Spiral 2D endovascular coil manufactured by Boston Scientific Corporation: general view **(A)**; fiber attachment **(B)**; interlock parts of coil and delivery system **(C)**; atraumatic tip **(D)**; interlocked coil and delivery system **(E)**

The Interlock Spiral 2D M00136155 coil (Boston Scientific Corporation) (Fig. 4) has much in common with the Nester and Flipper, but it is equipped with the groove-to-groove interlock mechanism held in engagement by the catheter tube of the delivery system. The interlock element (diameter 0.2 mm) is connected to the main coil by brazing. The polymer fibers are bundled together and evenly distributed between the spirals throughout the coil length. The atraumatic tip is made by brazing the platinum ball or reflow of the distal coil end.

The Interlock Spiral-35 M001363700 coil (Boston Scientific Corporation) (Fig. 5) is structurally identical to the previous model, but after the release from the delivery system the coil is not twisted into spirals, but is distributed in space in a chaotic manner. The polymer filaments, that are also bundled together, are longer than that of the Interlock Spiral 2D. The spherical atraumatic tip (0.8 mm) is produced by the reflow method. The interlock mechanism is tightly inserted in the coil without any traces of the glue or brazing, it is held by friction.

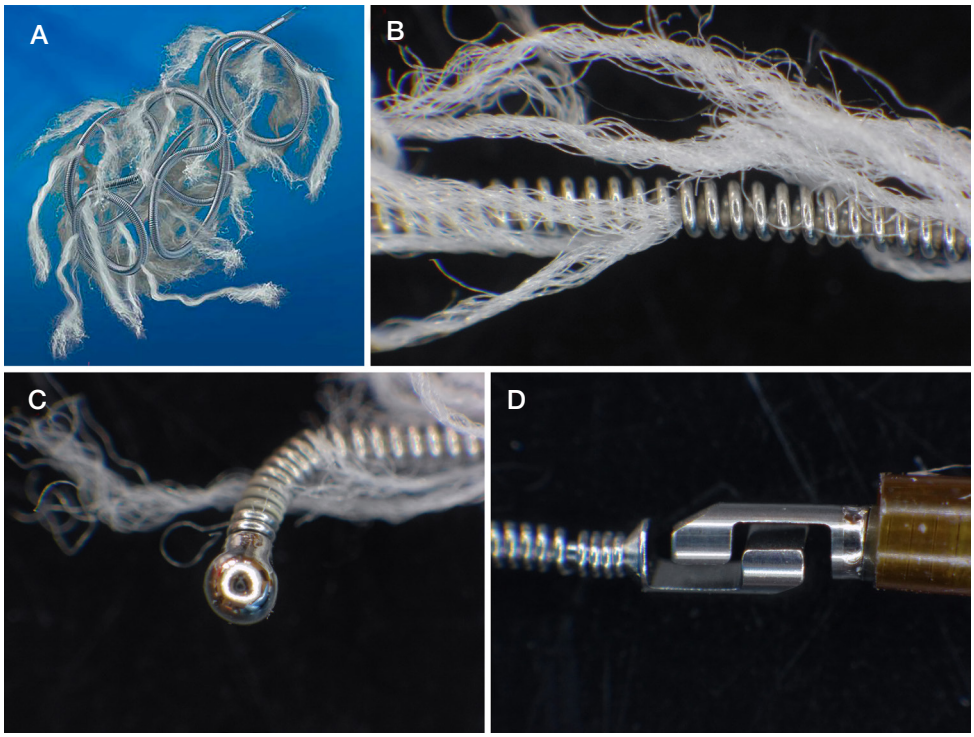

Fig. 5. Interlock Spiral - 35 endovascular coil manufactured by Boston Scientific Corporation: general view **(A)**; fiber attachment **(B)**; atraumatic tip **(C)**; interlock part of the coil **(D)**

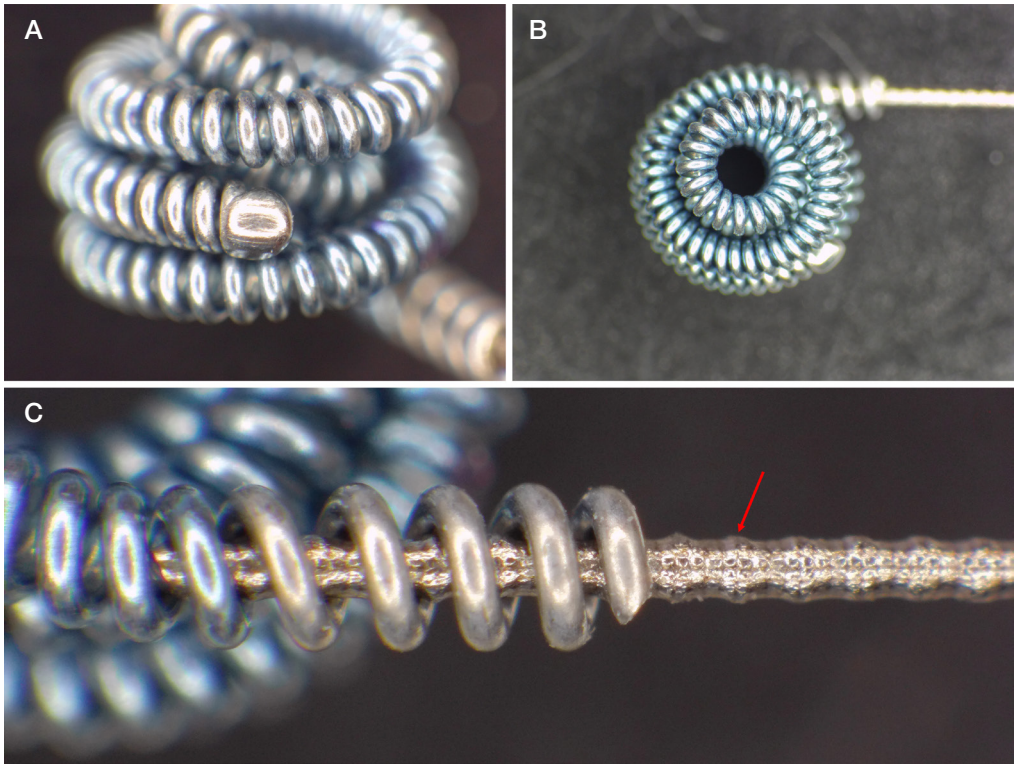

Fig. 6. Nit-Occlud PDA endovascular coil manufactured by PFM Medical GMBH: atraumatic tip **(A)**; general view **(B)**; interlock part, in which the screw notches on the delivery system rod for connection to the coil are pointed with the red arrow **(C)**

The Nit-Occlud PDA 145044V1 (PFM Medical GmbH) (Fig. 6) is the only coil considered that is made of titanium nickelide. After the release from the delivery system it is twisted into a tight stiff secondary coil. There are no polymer filaments. The interlock mechanism is realized through winding the turns of the coil onto the notches on the delivery system rod.

DISCUSSION

When developing sophisticated items, such as endovascular coils, the design team has to choose affordable materials and seek to maximize the structure simplicity and minimize the number of technological operations. This makes it possible to reduce the cost, waste, and the number of intermediate control stages.

The source wire diameter is the main factor determining the coil stiffness being the major selection criterion in endovascular surgery. With the emergence of soft, super-soft, and ultra-soft models, physicians now have an alternative to conventional stiff coils. Since soft coils are easier to insert in the affected area, practical understanding of their mechanical properties can help an endovascular surgeon select a certain coil [17]. Therefore, the coils made of the source wire 0.07 mm in diameter are considerably easier to install in the affected area compared to the coils made of the wire with the maximum diameter of 0.25 mm.

The presence of the atraumatic tip is an essential characteristic of the coil manufactured. The main complication of endovascular coiling is the risk of coil migration. The anchor coil technique is one of the key techniques reducing such risk [18]. The use of the coils with atraumatic tips allows the surgeon to minimize the risk of vascular wall perforation and endothelial damage, thereby increasing the intervention safety and contributing to its higher efficacy via reduction of the rate of intraoperative and postoperative complications.

The occlusion capability is likely to be the most important feature of any coil. The coiling technology is developed in order to improve the occlusion efficacy by adding various elements or changing the coil parameters that are usually aimed to improve thrombogenicity or packing tightness. Some earlier generation coils, such as Nester и Tornado (Cook Medical, Bloomington, Indiana), representing the pushed platinum coils made of platinum and nichrome, have the nylon bibers contributing to occlusion through stimulation of formation of the thrombus filling the space between the coil turns [19]. This technique was also realized in the detachable coils, for example in Concerto (Medtronic) [20]. Another approach is designing the coils so soft that these behave as a liquid metal, effectively filling the target space. An example are the Ruby family coils (Penumbra Inc, Alameda, California) [21]. Other products, such as AZUR CX Hydrocoil (Terumo Medical), have a hydrogel coating that expands after the delivery, filling the space between the turns [22]. The hydrogel starts expanding in 3 min and achieves the maximum width by 20 min. That is why the complete target vessel occlusion may need time. One of the papers presents the mid-term results of the use of the coils with the hydrogel and fibrous coating for arterial embolization in the animal experiment. In a month after the procedure the arteries embolized with the hydrogel-coated coils were 100% occluded. In 4 months the results were 80% [23]. Thus, coils with the hydrogel coating show a stable occlusion effect in the medium term.

The analysis of the coils reviewed has shown that the Flipper and Nester models have the simplest design in terms of production. Elements of the frames of these coils are made of different alloys, the glue is not used in the construct, and the processing tools are publicly available. At the same time, platinum is an expensive and not always freely accessible material. The melted tip production may require specialized laser equipment. Relative simplicity of the design of the above coils does not lower high efficacy and safety of the use of such devices for treatment of a broad spectrum of vascular disorders, mostly arteriovenous malformations and iatrogenic vascular complications. The analysis of the results of the retrospective

cohort study including 102 cases of endovascular embolization with the Nester and Flipper occlusion coils has shown that the technical success rate was 100%. The clinical efficacy determined as achieving the target blood vessel occlusion and symptom regression was reported in 98% of patients. In terms of safety, the intervention profile was beneficial: no severe adverse events associated with the device migration, mechanical destruction or periprocedural complications were reported [24].

The weak point of the Terumo AZUR coil is the interlock mechanism activated by the electric current. Such a detachment principle has indisputable advantages when used in the neuro-interventional procedures characterized by low blood flow rate. Such a design requires the development of the complex expensive electronic handle of the delivery system and the set of conductive elements. At the same time, when working inside peripheral blood vessels, the use of the coils equipped with the electrolytic detachment mechanism considerably limits the possibility of the implant postoperative maneuvering and positioning. Furthermore, the benefits of this technological solution remain unclear. The hydrophilic self-expanding sheath requires expertise and experience with such materials, as well as fixation with additional wire. At the same time, the use of the polymer atraumatic tip is a simple technological process that can provide the basis for the development of new coils.

The Interlock Spiral coils by Boston Scientific Corporation stand out due to the use of long sparsely arranged fibers for embolization, which simplifies the production process. However, the interlock mechanism is designed as two reciprocal cylindrical brackets, for the manufacture of which the expensive metalworking equipment is necessary, and high processing accuracy and the lack of sharp edges are critically important due to small size, to avoid damage to vessel walls after implantation.

In the Nit-Occlud coil PFM Medical GmbH refused to use polymer fibers, ensuring embolization due to the tightly twisted construct made of the elastic nitinol alloy. Nitinol produced by many companies is not subject to State control. The nitinol molding methods are well understood and realized using the affordable equipment. Simplicity of the interlock mechanism requiring no additional parts is one more benefit of such design.

It is important to develop a prototype based on the analysis of foreign analogues. However, the possibility of the endovascular coil import substitution is associated with a number of interrelated aspects requiring a comprehensive assessment. The analysis of the current situation on the Russian medical devices market demonstrates a steady upward trend in the share of domestic products [25]. According to the Consolidated Strategy on the Development of the Manufacturing Industry until 2030 and for the period up to 2035, in 2022, 26.8% of medical devices in the total market volume were of Russian origin, and it is planned to achieve the value of 36% by the year 2030, which is in line with the strategic goals of ensuring technological sovereignty in the critically important industries [26].

The institutional support by the State implemented through the subsidy, preferential loan, and tax preference mechanisms is the key factor of the domestic production development [25, 27]. These measures create economic incentives for localization of production, which is confirmed by the dynamics of the growth in the number of Russian enterprises in the field of medical devices and equipment [28]. However, the industry's technological readiness for production of endovascular coils is limited due to structural problems [26, 29]. The main barrier is the lack of full-cycle production, including the dependence on the imported substrates and specialized equipment for precision processing of materials. One more factor is the need for the products to comply with the ISO 13485 international standards and EEU requirements, determining the need for the quality control system modernization. It is worth noting a considerable financial barrier for bringing medical products to the Russian market. As of October 2023, the costs of registering one product in the Russian Federation reach 1.5–7 million rubles, and the time spent on issuing a registration certificate can be 3–18 months [28]. The prospects for overcoming the above barriers are associated with the implementation of the cluster approach involving integration of the scientific research institutions, production facilities, and clinical sites. Creation of competence centers in the field of biocompatible materials and additive technologies, which will make it possible to reduce dependency on the imported components, seems to be a priority [26, 30].

Thus, despite the existing technological and economic barriers, import substitution of endovascular coils in Russia has great potential. The key condition of success is the possibility of the shift from prototype development to serial production, which requires a systematic State support and extrabudgetary fund-raising.

CONCLUSIONS

Comparative analysis of the embolic coils produced by foreign manufacturers of medical equipment shows the dramatically different technical approaches to designing the devices similar in their purpose and effect. The alloys based on platinum, titanium nickelide and nickel-chromium alloy are used as the materials for coils. It is preferred that a polymer atraumatic tip and the "coil-core" interlock mechanism, along with the small diameter (in the range of 0.07–0.12 mm) nitinol wire as a material, are used to ensure the required biotechnical characteristics of the structure of the universal coil prototype. To determine the coil optimal shape and dimensions, it is planned to continue the study of their mechanical properties and polymer fibers used. The shift from prototype development to serial production of domestic embolic coils is possible, but it requires the creation of an appropriate technological base and significant investment costs.

References

1. Henkes H, Klisch J, Lylyk P. Will coiling survive through the next decade? J Clin Med. 2022; 11 (11): 3230. DOI: 10.3390/jcm11113230.
2. Yueqi Z, Hongbo Z, Yiran Z, Huayin W, Liming W, Gen Z, et al. Endovascular metal devices for the treatment of cerebrovascular diseases. Adv Mater. 2018; 30 (52): e1805452. DOI: 10.1002/adma.201805452.
3. Qiu MY, Suskin CB, Becerra-Garcia JJ, Roberts SH, Rucker DG, Zayed MA, et al. Quantification of the flexural rigidity of endovascular surgical devices using three-point bending tests. Res Sq. 2023. Preprint. DOI: 10.21203/rs.3.rs-3736325/v1.
4. Campos JK, Lien BV, Wang AS, Lin L. Advances in endovascular aneurysm management: coiling and adjunctive devices. Stroke Vasc Neurol. 2020; 5 (1): 1–8. DOI: 10.1136/svn-2019-000303.
5. Oka S, Kohno S, Arizono S, Onishi Y, Fumimoto M, Yoshida A, et al. Enhancing precision in vascular embolization: evaluating the effectiveness of the intentional early detachment technique with detachable coils in complex cases. CVIR Endovasc. 2024; 7 (1): 40. DOI: 10.1186/s42155-024-00453-7.

6. Xiao N, Lewandowski RJ. Embolic agents: coils. Semin Intervent Radiol. 2022; 39 (1): 113–118. DOI: 10.1055/s-0041-1740939.
7. Yuki I, Lee D, Murayama Y. Thrombus organization and healing in an experimental aneurysm model. Part II. The effect of various types of bioactive bioabsorbable polymeric coils. J Neurosurg. 2007; 107 (1): 109–120. DOI: 10.3171/JNS-07/07/0109.
8. White JB, Ken CG, Cloft HJ, Kallmes DF. Coils in a nutshell: a review of coil physical properties. AJNR Am J Neuroradiol. 2008; 29 (7): 1242–6. DOI: 10.3174/ajnr.A1067.
9. Cowley A, Woodward B. A healthy future: platinum in medical applications. Platin Met Rev. 2011; 55 (2): 98–107.
10. Kónya A, Maxin M, Wright KC. New embolization coil containing a nitinol wire core: preliminary in vitro and in vivo experiences. J Vasc Interv Radiol. 2001; 12 (7): 869–77. DOI: 10.1016/S1051-0443(07)61513-9.
11. Kobeiter H, Lapeyre M, Becquemin JP, et al. Percutaneous coil embolization of postcatheterization arterial femoral pseudoaneurysms. J Vasc Surg. 2002; 36 (1): 127–31. DOI: 10.1067/mva.2002.124372.
12. Yoshioka H, Kuroda C, Hori S, et al. Splenic embolization for hypersplenism using steel coils. AJR Am J Roentgenol. 1985; 144 (6): 1269–74. DOI: 10.2214/ajr.144.6.1269.
13. Oliver AA, Sikora-Jasinska M, Demir AG, Guillory RJ 2nd. Recent advances and directions in the development of bioresorbable metallic cardiovascular stents: insights from recent human and in vivo studies. Acta Biomater. 2021; 127: 1–23. DOI: 10.1016/j.actbio.2021.03.058.
14. Waldau B, Fargen KM, Mack WJ, Wilson NM, Khaldi A, Hoh BL, et al. Axium MicroFX coil for the Completing Endovascular Aneurysm Surgery Study (ACCESS). Interv Neuroradiol. 2012; 18 (2): 200–7. DOI: 10.1177/159101991201800213.
15. Fargen KM, Blackburn S, Deshaies EM, Carpenter JS, Jabbour P, Mack WJ, et al. Final results of the multicenter, prospective Axium MicroFX for Endovascular Repair of IntraCranial Aneurysm Study (AMERICA). J Neurointerv Surg. 2015; 7 (1): 40–43. DOI: 10.1136/neurintsurg-2013-011049.
16. Abi-Aad KR, Aoun RJN, Rahme RJ, Ward JD, Kniss J, Kwasny MJ, et al. New generation hydrogel endovascular aneurysm treatment trial (HEAT): a study protocol for a multicenter randomized controlled trial. Neuroradiology. 2018; 60 (10): 1075–84. DOI: 10.1007/s00234-018-2074-5.
17. White JB, Ken CG, Cloft HJ, Kallmes DF. Coils in a nutshell: a review of coil physical properties. AJNR Am J Neuroradiol. 2008; 29 (7): 1242–6. DOI: 10.3174/ajnr.A1067. PMID: 18417605; PMCID: PMC8119172.
18. Kanemaru K, Ezura M, Nishiyama Y, Yagi T, Yoshioka H, Fukumoto Y, et al. Anchor coil technique for arteriovenous fistula embolization. A technical note. Interv Neuroradiol. 2014; 20 (3): 283–6. DOI: 10.15274/INR-2014-10054. PMID: 24976089; PMCID: PMC4178771.
19. Liebig T, Henkes H, Fischer S, Weber W, Miloslavski E, Mariushi W, et al. Fibered electrolytically detachable platinum coils used for the endovascular treatment of intracranial aneurysms. Interv Neuroradiol. 2004; 10 (1): 5–26. DOI: 10.1177/159101990401000101.
20. Girdhar G, Read M, Sohn J, Shah C, Shrivastava S. In vitro thrombogenicity assessment of polymer filament modified and native platinum embolic coils. J Neurol Sci. 2014; 339 (1–2): 97–101. DOI: 10.1016/j.jns.2014.01.030.
21. Patel PJ, Arko FR 3rd. Ruby® coil and POD® system: a coil platform for fast and easy embolization. Endovasc Today. 2018; 17: 22–9.
22. Ferral H. Hydrogel-coated coils: product description and clinical applications. Semin Intervent Radiol. 2015; 32 (4): 343–8. DOI: 10.1055/s-0035-1564809.
23. Fohlen A, Namur J, Ghegediban H, Laurent A, Wassef M, Pelage JP. Midterm Recanalization after Arterial Embolization Using Hydrogel-Coated Coils versus Fibered Coils in an Animal Model. J Vasc Interv Radiol. 2019; 30 (6): 940–8. DOI: 10.1016/j.jvir.2018.05.005. PMID: 30174160.
24. Hochreiter-Hufford A, Gatz J, Griggs AM, Schoch RD, Birmingham KM, Frederick C, et al. Real-world data to support post-market safety and performance of embolization coils: evidence generation from a medical device manufacturer and data institute partnership. BMC Med Inform Decis Mak. 2024; 24: 263. DOI: 10.1186/s12911-024-02659-0.
25. Makarenko ED. Mekhanizmy prodvizheniya rossijskogo medicinskogo oborudovaniya na vnutrennem rynke. Finansovye rynki i banki. 2024; (3): 24–29. DOI: 10.24412/2658-3917-2024-3-24-29. Russian.
26. Rasporyazhenie Pravitel'stva Rossijskoj Federacii ot 06.06.2020 № 1512-r «Ob utverzhdenii Svodnoj strategii razvitiya obrabatyvayushchej promyshlennosti Rossijskoj Federacii do 2024 goda i na period do 2035 goda» (v red. ot 09.09.2023 № 2436-r, 07.11.2023 № 3113-r, 21.10.2024 № 2963-r). Russian.
27. Abdikeev NM. Realizaciya planov po importozameshcheniyu v vysokotekhnologichnyh otraslyah otechestvennoj promyshlennosti v usloviyah vneshnih sankcij. Nauchnye trudy Vol'nogo ekonomicheskogo obshchestva Rossii. 2022; (3): 202–14. Russian.
28. Hodos DV, Mushenko RD. Perspektivy razvitiya rynka professional'nogo oborudovaniya v usloviyah transformacii sfery medicinskih uslug v RF. EV. 2024; 1 (36): 92–100. DOI: 10.36807/2411-7269-2024-1-36-92-100. Russian.
29. Nahod VI, Krivenko AN, Butkova TV. Implantiruemye medicinskie izdeliya: obzor rynka. Zdorov'e megapolisa. 2024; 4 (1): 209–16. DOI: 10.47619/2713-2617.zm.2024.v.5i4p1. Russian.
30. Ershova EYu. Additivnye tekhnologii kak osnova narashchivaniya potenciala nacional'noj innovacionnoj sistemy. Vestnik Akademii znanij. 2025; 4 (69): 212–6. Russian.

Литература

1. Henkes H, Klisch J, Lylyk P. Will coiling survive through the next decade? J Clin Med. 2022; 11 (11): 3230. DOI: 10.3390/jcm11113230.
2. Yueqi Z, Hongbo Z, Yiran Z, Huayin W, Liming W, Gen Z, et al. Endovascular metal devices for the treatment of cerebrovascular diseases. Adv Mater. 2018; 30 (52): e1805452. DOI: 10.1002/adma.201805452.
3. Qiu MY, Suskin CB, Becerra-Garcia JJ, Roberts SH, Rucker DG, Zayed MA, et al. Quantification of the flexural rigidity of endovascular surgical devices using three-point bending tests. Res Sq. 2023. Preprint. DOI: 10.21203/rs.3.rs-3736325/v1.
4. Campos JK, Lien BV, Wang AS, Lin L. Advances in endovascular aneurysm management: coiling and adjunctive devices. Stroke Vasc Neurol. 2020; 5 (1): 1–8. DOI: 10.1136/svn-2019-000303.
5. Oka S, Kohno S, Arizono S, Onishi Y, Fumimoto M, Yoshida A, et al. Enhancing precision in vascular embolization: evaluating the effectiveness of the intentional early detachment technique with detachable coils in complex cases. CVIR Endovasc. 2024; 7 (1): 40. DOI: 10.1186/s42155-024-00453-7.
6. Xiao N, Lewandowski RJ. Embolic agents: coils. Semin Intervent Radiol. 2022; 39 (1): 113–118. DOI: 10.1055/s-0041-1740939.
7. Yuki I, Lee D, Murayama Y. Thrombus organization and healing in an experimental aneurysm model. Part II. The effect of various types of bioactive bioabsorbable polymeric coils. J Neurosurg. 2007; 107 (1): 109–120. DOI: 10.3171/JNS-07/07/0109.
8. White JB, Ken CG, Cloft HJ, Kallmes DF. Coils in a nutshell: a review of coil physical properties. AJNR Am J Neuroradiol. 2008; 29 (7): 1242–6. DOI: 10.3174/ajnr.A1067.
9. Cowley A, Woodward B. A healthy future: platinum in medical applications. Platin Met Rev. 2011; 55 (2): 98–107.
10. Kónya A, Maxin M, Wright KC. New embolization coil containing a nitinol wire core: preliminary in vitro and in vivo experiences. J Vasc Interv Radiol. 2001; 12 (7): 869–77. DOI: 10.1016/S1051-0443(07)61513-9.
11. Kobeiter H, Lapeyre M, Becquemin JP, et al. Percutaneous coil embolization of postcatheterization arterial femoral pseudoaneurysms. J Vasc Surg. 2002; 36 (1): 127–31. DOI: 10.1067/mva.2002.124372.
12. Yoshioka H, Kuroda C, Hori S, et al. Splenic embolization for hypersplenism using steel coils. AJR Am J Roentgenol. 1985; 144 (6): 1269–74. DOI: 10.2214/ajr.144.6.1269.
13. Oliver AA, Sikora-Jasinska M, Demir AG, Guillory RJ 2nd.

Recent advances and directions in the development of bioresorbable metallic cardiovascular stents: insights from recent human and in vivo studies. Acta Biomater. 2021; 127: 1–23. DOI: 10.1016/j.actbio.2021.03.058.
14. Waldau B, Fargen KM, Mack WJ, Wilson NM, Khaldi A, Hoh BL, et al. Axium MicroFX coil for the Completing Endovascular Aneurysm Surgery Study (ACCESS). Interv Neuroradiol. 2012; 18 (2): 200–7. DOI: 10.1177/159101991201800213.
15. Fargen KM, Blackburn S, Deshaies EM, Carpenter JS, Jabbour P, Mack WJ, et al. Final results of the multicenter, prospective Axium MicroFX for Endovascular Repair of IntraCranial Aneurysm Study (AMERICA). J Neurointerv Surg. 2015; 7 (1): 40–43. DOI: 10.1136/neurintsurg-2013-011049.
16. Abi-Aad KR, Aoun RJN, Rahme RJ, Ward JD, Kniss J, Kwasny MJ, et al. New generation hydrogel endovascular aneurysm treatment trial (HEAT): a study protocol for a multicenter randomized controlled trial. Neuroradiology. 2018; 60 (10): 1075–84. DOI: 10.1007/s00234-018-2074-5.
17. White JB, Ken CG, Cloft HJ, Kallmes DF. Coils in a nutshell: a review of coil physical properties. AJNR Am J Neuroradiol. 2008; 29 (7): 1242–6. DOI: 10.3174/ajnr.A1067. PMID: 18417605; PMCID: PMC8119172.
18. Kanemaru K, Ezura M, Nishiyama Y, Yagi T, Yoshioka H, Fukumoto Y, et al. Anchor coil technique for arteriovenous fistula embolization. A technical note. Interv Neuroradiol. 2014; 20 (3): 283–6. DOI: 10.15274/INR-2014-10054. PMID: 24976089; PMCID: PMC4178771.
19. Liebig T, Henkes H, Fischer S, Weber W, Miloslavski E, Mariushi W, et al. Fibered electrolytically detachable platinum coils used for the endovascular treatment of intracranial aneurysms. Interv Neuroradiol. 2004; 10 (1): 5–26. DOI: 10.1177/159101990401000101.
20. Girdhar G, Read M, Sohn J, Shah C, Shrivastava S. In vitro thrombogenicity assessment of polymer filament modified and native platinum embolic coils. J Neurol Sci. 2014; 339 (1–2): 97–101. DOI: 10.1016/j.jns.2014.01.030.
21. Patel PJ, Arko FR 3rd. Ruby® coil and POD® system: a coil platform for fast and easy embolization. Endovasc Today. 2018; 17: 22–9.
22. Ferral H. Hydrogel-coated coils: product description and clinical applications. Semin Intervent Radiol. 2015; 32 (4): 343–8. DOI: 10.1055/s-0035-1564809.
23. Fohlen A, Namur J, Ghegediban H, Laurent A, Wassef M, Pelage JP. Midterm Recanalization after Arterial Embolization Using Hydrogel-Coated Coils versus Fibered Coils in an Animal Model. J Vasc Interv Radiol. 2019; 30 (6): 940–8. DOI: 10.1016/j.jvir.2018.05.005. PMID: 30174160.
24. Hochreiter-Hufford A, Gatz J, Griggs AM, Schoch RD, Birmingham KM, Frederick C, et al. Real-world data to support post-market safety and performance of embolization coils: evidence generation from a medical device manufacturer and data institute partnership. BMC Med Inform Decis Mak. 2024; 24: 263. DOI: 10.1186/s12911-024-02659-0.
25. Макаренко Е. Д. Механизмы продвижения российского медицинского оборудования на внутреннем рынке. Финансовые рынки и банки. 2024; (3): 24–29. DOI: 10.24412/2658-3917-2024-3-24-29.
26. Распоряжение Правительства Российской Федерации от 06.06.2020 № 1512-р «Об утверждении Сводной стратегии развития обрабатывающей промышленности Российской Федерации до 2024 года и на период до 2035 года» (в ред. от 09.09.2023 № 2436-р, 07.11.2023 № 3113-р, 21.10.2024 № 2963-р).
27. Абдикеев Н. М. Реализация планов по импортозамещению в высокотехнологичных отраслях отечественной промышленности в условиях внешних санкций. Научные труды Вольного экономического общества России. 2022; (3): 202–14.
28. Ходос Д. В., Мушенко Р. Д. Перспективы развития рынка профессионального оборудования в условиях трансформации сферы медицинских услуг в РФ. ЭВ. 2024; 1 (36): 92–100. DOI: 10.36807/2411-7269-2024-1-36-92-100.
29. Наход В. И., Кривенко А. Н., Буткова Т. В. Имплантируемые медицинские изделия: обзор рынка. Здоровье мегаполиса. 2024; 4 (1): 209–16. DOI: 10.47619/2713-2617.zm.2024.v.5i4p1.
30. Ершова Е. Ю. Аддитивные технологии как основа наращивания потенциала национальной инновационной системы. Вестник Академии знаний. 2025; 4 (69): 212–6.