

Application of legally available medical devices as the basis of cosmetology clinic safety

© I.M. AKULIN¹, D.A. GRUZDEV², O.A. MAKHOVA¹, E.A. CHESNOKOVA¹

¹St. Petersburg State University, St. Petersburg, Russia;

²Association of Thread Implantologists, St. Petersburg, Russia

ABSTRACT

Objective. To study legal regulation for cosmetology clinics as subjects of circulation of medical devices and regulator's messages about prohibited medical devices.

Material and methods. We analyzed the regulatory legal acts of the Russian Federation defining mandatory requirements for medical devices. The reports of the Federal Service for Surveillance in Healthcare about medical products specific in cosmetology for all participants of the market were studied: threads, implant gels, biorevitalizants, cosmetology devices available with violations of legal requirements.

Results. Cosmetology clinics are prohibited by law from using unregistered, falsified, substandard, counterfeit or other medical devices withdrawn from circulation by regulator. One can receive information about registered medical devices and those that need to be discontinued on the Roszdravnadzor website. Roszdravnadzor published reports on 140 medical devices specific to cosmetology (threads, gel-implants (fillers), biorevitalizants, cosmetology equipment) for the period from 2012 to 2021. Percentage of medical devices illegally available in cosmetology has not decreased over the past 10 years (0.6% in 2021). Reports on illegally available cosmetology equipment prevail (59%, $p < 0.05$). Information about unregistered medical devices prevails with exception of implant gels ($p < 0.05$).

Conclusion. Percentage of medical devices illegally available in cosmetology has not decreased over the past 10 years. It is necessary to strengthen internal control over the safe use of medical devices in cosmetology clinics.

Keywords: medical devices, cosmetology, fillers, thread lifting, biorevitalizants.

INFORMATION ABOUT THE AUTHORS:

Akulin I.M. — <https://orcid.org/0000-0003-3945-6438>

Gruzdev D.A. — <https://orcid.org/0000-0002-8400-8311>

Makhova O.A. — <https://orcid.org/0000-0002-7765-4876>

Chesnokova E.A. — <https://orcid.org/0000-0001-6834-5687>

Corresponding author: Makhova O.A. — e-mail: wishtal@mail.ru

TO CITE THIS ARTICLE:

Akulin IM, Gruzdev DA, Makhova OA, Chesnokova EA. Application of legally available medical devices as the basis of cosmetology clinic safety. *Plastic Surgery and Aesthetic Medicine*. 2022;4:60–65. (In Russ.). <https://doi.org/10.17116/plast.hirurgia202204160>

Introduction

Currently, ensuring patient safety is a priority of medical activities [1]. The efforts are largely aimed at minimizing the risks associated with introduction of new innovative medical devices and strengthening internal control in medical organizations over their use [2].

Medical devices are a mandatory component underlying most services in cosmetology. Manufacturers regularly offer new types and models of medical devices for correction of skin aging. Various types of thread lifting, contouring and biorevitalization are widely used including combination with hardware cosmetology [3, 4]. High popularity of such methods is followed by certain complications which require correction by various medical devices [5, 6].

Importantly, many medical devices in aesthetic medicine are implantable and belong to high-risk devices [7].

Low-quality and falsified products comprise one of the problems in the use of medical devices [8].

In recent years, control over circulation of medical drugs at the post-registration stage has been strengthened in Russia. Violation of legal requirements entails prosecution, including criminal liability [9].

At the same time, the regulator (Roszdravnadzor) and experts emphasize a large amount of cosmetology services in the market illegally used in civil circulation [10, 11]. In this regard, application of only legal medical products is the most important safety element for conscientious managers of cosmetology clinics and cosmetologists along with such basic principles as the use by qualified specialists in strict accordance with documentation and sterility requirements.

The purpose was to study the regulatory framework for cosmetology clinics as subjects of medical device circulation, as well as the regulator's messages about medical devices whose application must be stopped.

Material and methods

We analyzed the regulatory requirements for cosmetology clinics as subjects of medical device circulation.

We estimated the information letters about medical devices posted on the official website of Roszdravnadzor (<https://roszdravnadzor.gov.ru>) for the last 10 years (from 2012 to 2021). Among all letters from Roszdravnadzor for

10 years (8583 ones), we distinguished 7213 letters related to illegally available medical devices (falsified, poor quality, unregistered, withdrawn from circulation, etc.). The letters of the supervisory authority prohibiting the use of certain medical devices specific for cosmetology (threads, gel-implants (fillers), biorevitalizants and cosmetology drugs) were studied.

Processing the data, we used the methods of analysis, synthesis, analogy and induction. Data are presented as absolute values and percentages. Categorical variables were compared using the chi-square test (χ^2).

Results and discussion

According to the Part 4 of the Article 38 of the Federal Law No. 323-FZ dated November 21, 2011 “On the Basics of Protecting the Health of Citizens in the Russian Federation” [12], legally available medical devices should pass state registration in the manner established by the Government of the Russian Federation, as well as in accordance with international treaties and acts constituting the law of the Eurasian Economic Union. Certain exceptions allow the use of medical devices without registration by law in some cases. However, these exceptions do not apply to cosmetology clinics.

A register of legal medical devices is available on the official website of the Roszdravnadzor (section “Electronic Services”).

As a part of the MEDICRIME Convention, article 38 of this law included the following groups of medical devices prohibited for use: falsified, low-quality and counterfeit products.

Falsified medical devices are accompanied by false information about their characteristics and/or manufacturer.

Poor-quality medical devices do not meet the safety and efficiency requirements for labeling, regulatory, technical and operational documentation. These devices cannot be safely used for the intended purpose established by the manufacturer. The last requirement was added in 2021. This makes it possible not to exclude medical devices with formal labeling violations and inconsistencies with the registration dossier that do not lead to violations of safety requirements. Medical device is recognized as substandard after examination of quality, effectiveness and safety.

Counterfeit medical devices are available with violations of civil law. As a rule, we mean parallel imported medical devices. These are original goods marked with a trademark by the right holder himself and imported into the territory of the Russian Federation without consent of the manufacturer. Prevention of parallel import is a problem of the right holder as the subject of infringed trademark rights. Medical devices are determined to be counterfeit by court order. Counterfeit goods on the market to a lesser extent affect safety of cosmetology services.

According to the current legislation, falsified and low-quality medical devices are subject to seizure and subsequent destruction or exportation from the Russian Federation on the basis of decision of their owner, Roszdravnadzor or court decision. Counterfeit medical devices are subject to seizure and subsequent destruction by a court decision.

The owner reimburses expenses associated with withdrawal from circulation and destruction of falsified, substandard and counterfeit medical devices. Exportation of falsified and substandard medical devices from the Russian Federation is carried out at the expense of the person who imported them into the Russian Federation [12].

The contracts for supply of medical devices to medical organizations often stipulate responsibility of the supplier for the quality of the goods and obligations to destroy and/or replace the goods if necessary.

If such products are detected, Roszdravnadzor suggests that the subjects of circulation (including cosmetology clinics) check whether a particular medical device, model (variant), batch or series is available with violations of current legislation and prevent circulation of these devices in the Russian Federation. Medical organization should report the results of these measures to the territorial office of Roszdravnadzor.

Up-to-date data are presented to the subjects of circulation including by posting information letters (messages) on the official website of Roszdravnadzor.

Roszdravnadzor published the reports on 140 medical devices available in cosmetology between 2012 and 2021 (7213 letters).

Percentage of messages about cosmetic products among all illegally available medical devices was similar in 2012 and 2021 (1.1 vs. 0.6%, χ^2 0.002, $p > 0.05$). At the same time, analysis of time series shows significant (by 12.4%) growth in 2013 ($p < 0.05$) with subsequent decrease (**Fig. 1**).

Structure of information letters from Roszdravnadzor on cosmetic products in 2012–2021 is shown in **Fig. 2**.

Reports of illegally available cosmetic devices prevailed ($n=83$ (59%), χ^2 11.724, $p < 0.01$). There were 34 (24%) reports about various types of threads, 15 (11%) letters about fillers and 8 (6%) reports about biorevitalizants.

Unregistered medical devices prevail in general and in certain groups with the exception of implant gels (fillers) (122 (87%), χ^2 30.663, $p < 0.01$) (**Fig. 3**).

The following are examples of non-registered medical devices:

— cosmetology devices (“Multifunctional cosmetology device NV-1608 PRETTY BABY”, NEWFACE, letter No. 01И-17/18 dated 01/11/2018);

— fillers (in accordance with the letter No. 01И-1010/18 dated 04.24.2018, “FEEL DERLI Strong+ water-containing CONTOURGEL-KHPM filler” (Khimpolymed LLC) is not subject to the registration certificate No. FSR 2007/00256 dated 07/30/2007 due to the identified inconsistencies);

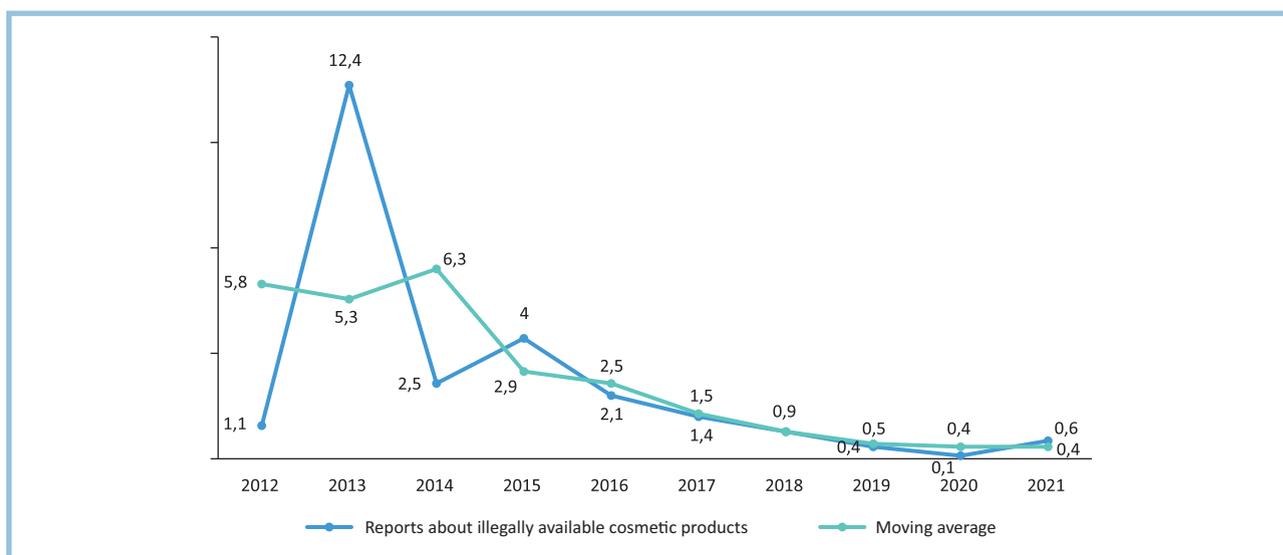


Fig. 1. Reports about illegally available cosmetic products among all letters about medical devices in 2012–2021 (%).

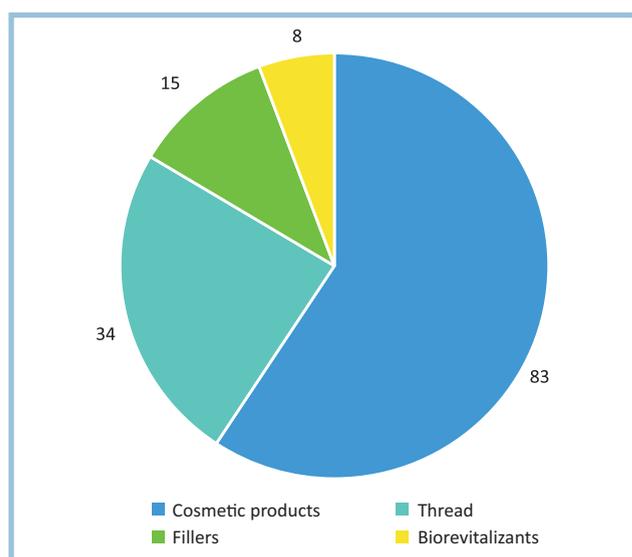


Fig. 2. Structure of Roszdravnadzor letters on cosmetic products in 2012–2021.

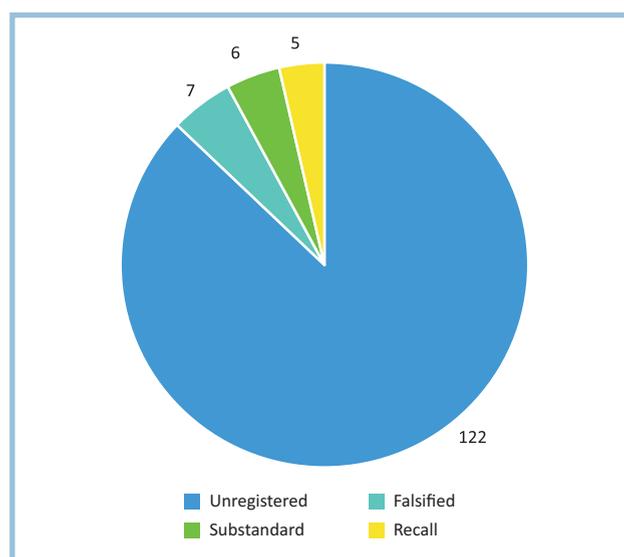


Fig. 3. Structure of Roszdravnadzor letters on cosmetic products in 2012–2021 depending on the type of prohibited medical device.

— biorevitalizants (“Biorevitalizant-skinbooster Overage MESO, 23 mg/ml, 1.0 ml” manufactured by Mesotech s.r.L, Italy, letter No. 01И-2940/17 dated 11/28/2017).

Unregistered mesothreads are regularly detected. For example, several types of Korean threads were withdrawn from circulation in 2015 including “Mesothreads Multi Lifting V-Line (Polydioxanone suture).

Roszdravnadzor identifies the falsified medical devices, for example:

— “Ulthera System ultrasonic device for dermatology and cosmetology with accessories” (letter No. 01И-1579/20 dated 08/17/2020);

— “Softlift-C monosorb M3 threads with opposite notches USP 2-0 (EP ZU thread length 600 mm)

/ straight needle 150 mm, d-1.2” (letter dated No. 01И-1324/20 07/10/2020);

— implantable gel for intradermal injections HYALAX Revitalize Skin, lot 403027 (letter No. 01И-209/16 dated 02/08/2016).

The following are examples of poor-quality medical devices:

— cosmetic threads, for example “Lead Fine Lift sterile absorbable polydioxanone threads for tissue lifting on carrier needles of various sizes”, LOT 276051A (MEDIFIRST Co., LTD, Korea), registration certificate No. ФС3 2012/13378 dated 12/14/2012 (Roszdravnadzor letter No. 01И-162/17 dated 01/24/2017);

— apparatus for local darsonvalization and galvanization AmDG “ISKRA-4”, TU 9444-003-34711238-

2005 (JSC Novoanninsky Plant EMA, Russia) (Roszdravnadzor letter No. 01I-140/20 dated 01/21/2020).

In some cases, the manufacturer voluntarily recalls medical devices. For example, the manufacturer of “Etermis gel-implant for intradermal use” (Merz Pharmaceuticals GmbH, Germany) voluntarily recalled some series due to particles in some Etermis syringes not listed in the composition (Roszdravnadzor letter No. 01I-464/21 dated 04/12/2021).

Acceptance of medical devices is important stage, and employees of cosmetology clinics need to be extremely careful and attentive to incoming products and documentation.

It is advisable to check the information about registration certificate on official website of Roszdravnadzor (<https://roszdravnadzor.gov.ru/services/misearch>) before ordering a specific product asking the supplier for the full name or article number.

The State medical registry is publicly available, and no authorization is required. One can search for registration certificates not only by the name of medical devices, but also 16 additional positions. When necessary registry entry is found, you can download registration certificate, photographic images, instructions for a particular medical device and data on changes made to registration documents.

The following signs of unregistered medical devices can be distinguished:

- no registration certificate (no data in state register);
- medical device is accompanied by registration certificate, but its name, composition and accessories do not correspond to the information specified in the registration certificate;
- name and/or address of the manufacturer do not correspond to information specified in the registration certificate.

Responsible persons of medical organizations must regularly control the data on the Roszdravnadzor website to exclude illegal medical devices.

The Register of Information Letters on Medical Devices (<https://roszdravnadzor.gov.ru/services/unreg>) is also publicly available, does not require authorization and contains all the necessary criteria for optimized searching. Thus, the person in charge can control all new letters published, for example, over the past week. Moreover, one can regularly receive up-to-date information on legality of medical devices available in civil circulation.

If illegally available medical devices are detected at the stage of acceptance or after receiving the information from Roszdravnadzor, employees of medical organiza-

tions should move medical devices from the main storage area to the special quarantine storage area until publication the information letter about resumption of application. In case of withdrawal, it is necessary to draw up an act indicating the cause of withdrawal and send information to Roszdravnadzor.

The mechanism for monitoring of safety of medical devices is important in identifying illegally available medical devices. This mechanism implies systematic joint work of manufacturers, medical organizations and regulator devoted to identifying, analyzing, recording and correcting all possible risks and defects that were not previously taken into account. This work is aimed at improving the efficiency and safety of medical devices [9]. Medical organizations are responsible for informing Roszdravnadzor and manufacturer about all side effects not specified in instructions, adverse reactions, other facts and circumstances that pose a threat to the life and health of patients and medical workers (signs of marriage in cosmetology clinics) [12]. After receiving the information, Roszdravnadzor and the manufacturer take necessary measures, including expert examinations. After that, medical device, its model (variant), batch or series can be withdrawn from circulation.

Medical organization can send information in several ways, including on paper. The most optimal way is the automated system “Safety Monitoring of Medical Devices” after authorization (<https://roszdravnadzor.gov.ru/services/servicemonitoringMI>).

In cosmetology clinics, one employee is usually responsible for accepting and identifying illegally circulating medical devices and medicines, sending information to Roszdravnadzor and other aspects of safe application of medical products. This work should be regular and systematic.

Conclusion

Percentage of medical devices illegally available in cosmetology has not decreased over the past 10 years. It is necessary to strengthen internal control over the safe use of medical devices in cosmetology clinics at the stages of acceptance and application. Control of information from Roszdravnadzor reduces the threat to patient health following the use of low-quality products, as well as financial and reputational risks for cosmetology clinics.

Funding. The study had no sponsorship.
The authors declare no conflicts of interest.

REFERENCES

1. Murashko MA. Vremya innovatsij (po materialam konferentsii “Farmmed-obrashchenie-2019”). *Vestnik Roszdravnadzora*. 2019;3:5-20. (In Russ.). https://doi.org/10.35576/article_5d135f4a303e79.40852
2. Makhova OA. Application of medical products: mandatory requirements, supervision of their compliance. *Farmakoekonomika. Modern Pharmacoeconomics and Pharmacoepidemiology*. 2021;14(4):515-522. (In Russ.).

- <https://doi.org/10.17749/2070-4909/farmakoeconomika.2021.075>
3. De Melo F, Carrizo A, Hong K, et al. Minimally Invasive Aesthetic Treatment of the Face and Neck Using Combinations of a PCL-Based Collagen Stimulator, PLLA/PLGA Suspension Sutures, and Cross-Linked Hyaluronic Acid. *Clinical, Cosmetic and Investigational Dermatology*. 2020;13:333-344. <https://doi.org/10.2147/CCID.S248280>
 4. Gruzdev DA, Ovchinnikova DV, Kodyakov AA. Kompleksnoe omolozhenie kozhi litsa s ispol'zovaniem nitevykh metodov. *Metamorfozy*. 2016;13:36-41. (In Russ.).
 5. Ikonnikova EV, Manturova NE, Kruglova LS, Potkin SB. Oslozhenie nitevogo liftinga na fone konturnoy plastiki litsa: klinicheskij sluchaj. *Klinicheskaya dermatologiya i venerologiya*. 2021;20(2):97-102. (In Russ.). <https://doi.org/10.17116/klinderma20212002197>
 6. Aksenenko IP. Sochetannoe primeneniye fermento- i karboksiterapii pri oslozheniyakh konturnoy plastiki oblasti kisti v kosmetologii. *Fizioterapiya, bal'neologiya i rehabilitatsiya*. 2020;19(2):83-89. (In Russ.). <https://doi.org/10.17816/1681-3456-2020-19-2-3>
 7. Prikaz Ministerstva zdravookhraneniya Rossijskoj Federatsii ot 6 iyunya 2012 g. No. 4n "Ob utverzhdenii nomenklaturnoj klassifikatsii meditsinskih izdelij". (In Russ.). Accessed March 14, 2022. <https://www.garant.ru/products/ipo/prime/doc/70099586/#review>
 8. Global'naya ramochnaya model' VOZ po regulirovaniyu meditsinskih izdelij, v tom chisle meditsinskih izdelij dlya diagnostiki *in vitro*. (In Russ.). Accessed March 14, 2022. https://www.euro.who.int/data/assets/pdf_file/0003/356484/WHO_GlobalModelRegulatorFramework_2017_ru.pdf?ua=1
 9. Akulin IM, Makhova OA, Chesnokova EA. *Obespechenie bezopasnosti pri primeneni meditsinskih izdelij*. M.: Direkt-Media; 2021;280. (In Russ.).
 10. V svyazi s vozroschim kolichestvom oslozhenij u patsientov posle kosmetologicheskikh protsedur Roszdravnadzor zayavlyayet sleduyushchee: ofits. tekst. [Elektronnyj resurs]. (In Russ.). Accessed March 14, 2022. <https://roszdravnadzor.gov.ru/news/11463>
 11. *Vse ottenki serogo: pochemu rossijskij rynek kosmetologicheskikh in'ektsij izoshchrenno soprotivlyaetsya "obeleniyu"*. Delovoj zhurnal ob industrii zdorov'ya VADEMECUM [sajt]. (In Russ.). Accessed March 14, 2022. https://vademec.ru/article/vse_otsenki_serogo-_pochemu_rossiyskiy_rynok_kosmetologicheskikh_inektsiy_izoshchrenno_soprotivlyaet/
 12. Federal'nyj zakon Rossijskoj Federatsii ot 21 noyabrya 2011 g. No. 323-F3 "Ob osnovakh okhrany zdorov'ya grazhdan Rossijskoj Federatsii". (In Russ.). Accessed March 14, 2022. <https://base.garant.ru/12191967>

Received 15.09.2022

Accepted 17.10.2022