STATEMENT
Head of the branch office
"Interdistrict Oncology Center"
Health Institution "Pinsk Central Polyclinic"
_____ Kochanovich S.V.
18th of June 2015

Record № 1 dated 16th of June 2015
"About realization of medical tests of a medical product: carbon fiber sorbtion sterile cloth brand AUT-M TU RB 00204056, 076-99 in the form of napkins (mm sizes, 150x135, 100x100)".

MANUFACTURER:
OJSC "SvetlogorskKhimvolokno"
Republic of Belarus, 247400, Gomel region, Svetlogorsk, Zavodskaya, 5

The purpose of tests:
Assessing the possibility of application the products which are mentioned above in medical practice in medical institutions in Belarus.

For test were given:
A set of documents on the product, a registration certificate and advertising materials; instruction on the application, product samples.
The task of clinical approbation was primarily in the need to examine and determine possibility of applying napkins in the medical practice of medical institutions of Belarus.

Stages of trials:
1) The preliminary stage: working with documents - the study of completeness, quality documentation. Determination of conformity "carbon fiber sorbtion cloth AUT-M" with the basic requirements for application.
2) The clinical application of "carbon fiber sorbtion cloth AUT-M" with the assessment results.

Description and purpose of the product:
The carbon fiber sorbtion sterile cloth brand AUT-M production of "SvetlogorskKhimvolokno" in individual packages, according to TU 0024056.076-99 material matt black color without shine, made on the basis of viscose yarn, consist of medical and sorbent napkins the following sizes: 150x135 mm, 100x100 mm.

The carbon fiber sorbtion sterile cloth brand AUT-M production of "SvetlogorskKhimvolokno" in individual packages, according to TU 0024056.076-99, made of activated carbon fibers with a well-developed micro, meso and macroporosity. The production process includes the steps of carbonization and activation. Napkins are sterile for at least five years from the date of sterilization.

The carbon fiber sorbtion sterile cloth brand AUT-M of "SvetlogorskKhimvolokno" in individual packages, are designed for the treatment of wounds of various etiology, prevention of wound infection and pyoseptic complications.

Carbon absorbing medical napkins disinfectant and purified wounds by neutralization of toxic substances in the wound. They are used to normalize the pH of body tissues and drainage fibro-

purulent exudates, adsorption of specific purulent odor, elimination of pain and destruction of the newly formed tissue dressings or allergy to the use of other medications, for healing and rehabilitation, etc.

Sorbent and medical napkins do not injure the surface of the wound when dressings changes, remain under the wound a layer with wound exudates, which has a beneficial effect on epithelialization.

Medical sorption properties of the napkins lead to the rapid purification of wounds in the inflammatory phase and allows the use of impregnate napkins medications without removing the bandage from the wound. It eliminates of necessity of frequent and painful dressings changes, created comfort for patients and reduces the consumption of analgesics.

Each medical napkin production of "SvetlogorskKhimvolokno" in individual packing is made from carbon fiber sorbent applied at treatment of soft tissue injuries of different etiologies (burn wounds, the wounds in open fractures, decubitus ulcers and trophic ulcers) at all stages wound healing process. Even without medicaments, it does not allow wound infection, not "dry on" to it quickly reduces inflammation and swelling.

Used for treatment of purulent and slowly healing wounds, trophic ulcers, burns, fistulas, postoperative wound complications. Efficiency of napkins based on its high porosity and capillary activity. This napkin absorbs micro-organisms, chemicals, purulent discharge. It relieves pain, has a hemostatic action, absorbs odor and does not cause side effects.

Indications for use:

- Wounds of traumatic origin;
- surface and deep burns;
- trophic ulcers;
- pyonecrotic wounds;
- Chronic poorly healing wounds;
- bedsores, fistulas.

Fields of application:

Napkins are designed for use in the both inpatient and outpatient health care institutions for the treatment of both superficial and deep wounds and injuries or wounds various etiologies.

Indications for use of dressings:

Napkins are used to treat a variety skin injuries and covers, surgical and non-surgical wounds such as bedsores, venous ulcers, diabetic ulcers, burns and wounds remaining after skin transplantation etc. (For external use only).

Materials of clinical trials:

Selection of patients for trials is carried out after a preliminary examination and reception of agreement for the planned using of the test samples. The total number of patients was 6 patients.

The research was conducted with patients with the following pathological symptoms:

- 2 patients - with bedsores;
- 2 patients - treatment of granulating wound surfaces;
- 1 patient - treatment of "donor" wounds (after collection of free-split skin flaps for transplantation), complicated by inflammation;
- 1 patient - treatment of "donor" wounds (immediately after collection of free-split skin flaps for transplantation).

Results of clinical trials:

It should be noted that the following information is not the result of randomized research, we can not carry out, and is a subjective opinion of leading oncologists and surgeons of our organization

(the Head of a Branch Kokhanovich S.V., Head of Oncology Dept. an oncologist-surgeon of the highest category Sachkovsky S.N., Head of operational and dressings Dept. oncologist-surgeon of the highest category Smuraga D.A., oncologist-surgeon of the highest category Romanchuk A.N.), based on our clinical experience.

In our department of oncological surgery (60 beds) sorbent carbon cloth AUT-M was used, according to instructions for the treatment of infected wounds, septic wounds, bedsores and also for the treatment of "donor" wounds (after collection of free-split skin flaps), complicated by inflammation . Application time a single napkins sorbent carbon cloth AUT-M was 1-2 days, and then, if necessary, replace the napkin, or remove it and continue the further treatment of the wound.

Our experts have identified the following advantages of using the napkins sorbent carbon cloth AUT-M in the treatment of wounds of various etiologies (both separately and combined treatment):

1. The material does not injure the surface of the wound during dressing changes, remains under itself a layer of wound exudates, which has a beneficial effect on epithelialization (in all groups of patients it was noted some improvements to compare with control group).

2. High sorption properties of the material can achieve rapid cleansing wounds in the inflammatory and necrotic and inflammatory stages, and also use the method of impregnating the medications without removing the dressing from the wound surface. The materials stimulate the growth of granulation without disrupting the blood supply, causing possible to achieve rapid growth of rich, viable granulations.

3. Compared to other methods of treatment: the application of carbon napkins "SvetlogorskKhimvolokno" does observation of vastness and depth of the wound is extremely favorable.

4. Change of dressings is almost painless. Elimination of the need of frequent dressings contributed to significant savings dressing materials, medicaments and staff time.

5. While using of napkins, any adverse reactions to napkins AUT-M have not been noticed by professionals and patients.

6. Many patients notice an increase of comfort of treatment, including the presence of large infected wound surface, reducing of pain syndrome, the possibility of a quick recovery, improvement of general condition.

When using the test product in surgical practice in the treatment of wounds noted the following positive results:

- reduction in the degree of invasiveness of many sanitizing operations;
- reduction in the rate of complications in the surgical wound readjustment;
- reduction of the period of conservative local treatment of patients with chronic wounds in approx. one third;
- after 3-4 days of application of napkins there was a clear reduction of purulent discharge, disappeared pain, redness and swelling of the soft tissue surrounding the wound, reduction of the area of wound surface; with continued therapy development of regeneration processes significantly grew. Also napkins had a positive effect on the processes of epithelialization.

CONCLUSION:

According to the results of trials, the test product carbon fiber sorbtion cloth brand AUT-M produced by "SvetlogorskKhimvolokno" in individual packaging TU 0024056.076-99 are reliable, convenient in using and correspond with the level of security for this type of material.

A medical product fully complies with the requirements of the modern practice of medicine.

The researches allow to recommend this medical product: napkins "carbon fiber sorbtion cloth brand AUT-M", production of "SvetlogorskKhimvolokno" in individual packages, according to

TU 0024056.076-99 for use in medical institutions in Belarus and can be recommended in health and social development of Republic of Belarus.

Note:

- We also consider it appropriate to use the napkins "carbon fiber sorbtion cloth brand AUT-M" in palliative medicine: the dressings changes while outpatient and inpatient treatment, oncology patients with large ulcerated tumors of the soft tissue - in order to improve the comfort of palliative treatment, reducing the frequency of dressings, reduce pain and absorption of odors.

- In case of beginning of industrial production of napkins "carbon fiber sorbtion cloth brand AUT-M" - please, inform our organization about the possibility of inclusion napkins "carbon fiber sorbtion cloth brand AUT-M" in the list of supplies of operational and dressing materials for purchasing in 2016 (when price is provided).

Acting Head of operational and dressing unit of the Branch of "Interdistrict Oncology Center"

Health Institution "Pinsk Central Polyclinic" *Smuraga D.A.*