*Prevents* *suffering from dry lips*
*Safeguarding* *patients from HAI's*
*Maximizing* *patient well-being*

**IMD tec hereby recommends a medical device targeted, among others, at hospital acquired infections (HAI), which is all the more important today in face of the coronavirus pandemic. Though it provides no direct medical solution for this virus, it may directly safeguard the hospitalized against such infections.**

Acquired infections, also known as “nosocomial infections”, are contracted by patients during their stay in hospitals as well as in other medically-related institutions, i.e. nursing homes etc. Such infections were not at the active or incubation stage before the patient’s admission to the institution, and may also appear after the patient has been released. Moreover, they may affect the medical staff.

Acquired infections can be caused by different strains of viruses (parasites without enzymes or mechanisms required for reproduction, such as COVID-19, which has nowadays shut down the whole world and endangered the lives of thousands), germs, fungi and parasites. These infections account for a significant share of hospitalization-related complications, which may lead to morbidity and mortality.

Acquired infection in medical institutions is a worldwide phenomenon. E.U. estimates stand at around 4 million infected patients in medical institutions across Europe, with app. 147,000 directly resultant deaths. U.S. Center for the Prevention and Control of Diseases records 700,000 patients with acquired infections in general hospitals per year, and 75,000 deaths; Israel’s Ministry of Health reports 4,000-6,000 deaths from acquired infections.

The World Health Organization (WHO) indicates a number of causes for the spread of acquired infections in hospitals, ranking highly that of “deficient hygiene”. The last decade has furthered understanding of the transmission process of these infections (germs, viruses) via hand contact, making clear that prevention depends on antiseptic hand hygiene, including washing or disinfections. However, response to hand hygiene regulations by the medical staff is inadequate. The reason for this are the conditions in the various wards, which impose on the staff heavy workloads, contact (with patients) requiring multiple handwashing, and the time-consuming process of efficient handwashing.

In industry, manual work has been decreased and replaced by atomization (improved and efficient quality of production.....). In the medical field, hand contact should also be minimized (contact devoid of antiseptic hand hygiene exposes patients to the risk of acquiring infections).

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This understanding compels urgent implementation, especially in view of the coronavirus outbreak and desperate attempts to decrease infection by adhering to hand hygiene, most particularly in such cases applicable to a simple and available solution:

Patients recovering from full anesthetic surgery are prevented from drinking water for a number of hours (depending on the type of operation), about 60% experience dryness on their lips at different levels, with 7 being the average on a scale from 1 to 10. These patients need their lips to be hydrated frequently, in one way or another. So far, as against the ever-increasing progress in medical treatment, lip-hydration is carried out manually by a staff member or family member of the patient that in turn increases the danger of acquired infections due to deficient hand hygiene.

Lipsus is an automatic perishable device for hydrating lips. The one-time setup is simple and frees the medical staff or family members from manual hydration of the patients' lips during the whole period of abstention from drinking water. Moreover, in addition to the great advantages of regular and measured lip-hydration, Lipsus also decreases the hand contact between patients and medical staff or family members, safeguarding hospitalized against acquired infection (HAI). In addition with no less importance, the workload of the medical staff is decreased, allowing them to carry out other essential duties.

Abstention from drinking water for a number of hours extends not only to cases of post-anesthetic surgery, but also to many medical conditions, such as fasting before general anesthesia, cancer patients during chemotherapy, geriatric patients suffering from a dysfunctional salivary gland and others.

The Lipsus device positions a moist, soft and pleasant-to-the touch material (non-woven) within reach of the patient's dry lips by placing a plastic arch, similar to a pair of glasses, on the head of the patient including two ends, which fit behind the patient's ears.

The moisture in the material is maintained at a regular level and is continuous without any external interference because of a flow control element in the Lipsus device adjusted to 12-15 (cc/hr), which is positioned near the moist material. The water is supplied in an infusion bag containing 300 cc (tap, or mineral water) which hangs on a standard infusion stand at a height of 70-120 (cm) above the patient's head. The water flows from the fusion bag through a flexible plastic tube with an internal diameter of 3 mm and 150 cm in length.


This device is disposable and used only once.

The Lipsus device was developed by IMD Tec.

The device is manufactured by Shahak-Tec Ltd. according to the medical device standard ISO13485.

The device has all the required approvals: CE, FDA, and approval from the Israeli Medical Device Authority.

The device successfully passed clinical tests in Shaare Zedek Medical Center and during the last few months, hundreds of devices (Lipsus) have been supplied to a number of leading hospitals in Israel. Their feedback has been very positive.

The device will be distributed in Israel by Medici Medical Ltd. which serves as a group purchasing organization (GPO) for governmental hospitals, medical centers and various Israeli institutions, including public health services, local health offices, the emergency department at the Ministry of Health, and other organizations.

**Additional documents:**

- Approval from the Israeli Medical Device Authority
- FDA approval
- CE approval
- A clinical experimental report