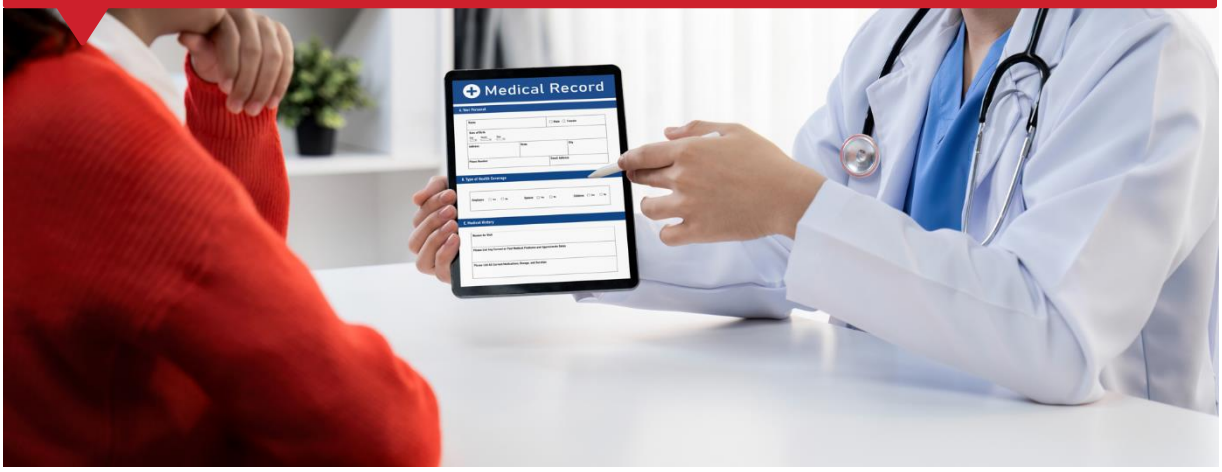
IMPLANT CARDS



If our medical device OKCEL® was used during surgery, please pay attention to the following information. OKCEL® is a local absorbable haemostatic (a device to support the bleeding stop). Because it is a degradable medical device, it is not always necessary to remove it after the bleeding has stopped and it can be left in the body. Despite all the care taken by Synthesia, a.s., as a manufacturer, dedicated to this product and which doctors dedicate to your health, complications may arise. This is why you have been informed about the use of the medical device and have been given an Implant Card.

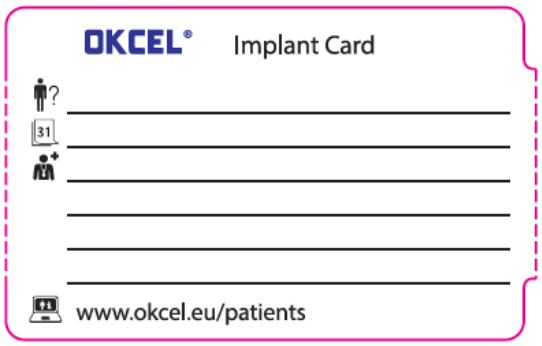
What is the *Implant Card* and what information does the *Card* contain?

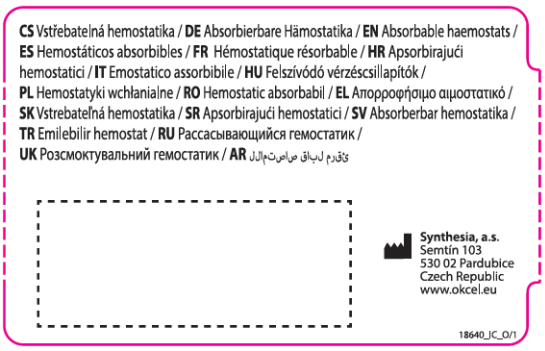
The *Implant Card* is a document for the patient that contains:

- on the one hand, information about the medical device – the implant, which was inserted into the patient's body during the clinical procedure;
- on the other hand, information about the patient to whom the device has been implanted and the health care facility in which the procedure was performed.

The front of the *Implant Card* contains the name of the document in English, the name of the medical device, your identity, the date the medical device was used and introduced into the body, information about the health care facility that performed the procedure, and a link to the medical device manufacturer's website.

The information on the *Implant Card* is assigned to the appropriate symbols, which are summarized in the table below.





On the back of the *Implant Card*, a symbol

MD

is used to indicate that it is a medical device. This symbol is followed by the name of the device and the used form, namely OKCEL® H-T, OKCEL® H-D, OKCEL® F, or OKCEL® S. More detailed information on particular forms is given below.

On the back of the *Implant Card*, there are additionally used symbols with data, 2D code and UDI-DI. This information identifies the medical device used. UDI-DI is a numeric code assigned for each catalogue number (REF) - defines which variant (form and size) of the medical device was used. The list of manufactured forms and variants according to the catalogue number can be found below.

Table 1: **Information on the symbols used on the *Card*.**

Symbol	Description	Symbol	Description
	Patient identity	UDI	Unique device identifier
	Date of implantation	REF	Catalogue number
	Name and address of the health care facility	LOT	Batch code – includes medical devices manufactured under the same conditions
	Information website for patients		Use-by date – indicates the date after which the medical device is not to be used
MD	Medical device		Manufacturer

What is OKCEL® and what forms of OKCEL® medical device do we produce and how do they differ?

Synthesia, a.s. manufactures absorbable oxidized cellulose OKCEL® as a sterile absorbable medical device in the form of knitted fabric (OKCEL® H-T and OKCEL® H-D) or soft layered material (OKCEL® F and OKCEL® S). It is prepared by controlled oxidation of cellulose, which comes from high-quality cotton fibre.

This medical device is used in defined cases adjunctively during surgical and mini-invasive procedures to control bleeding. It is a so-called *local haemostat*.

OKCEL® H-T is a standard density knitted fabric and OKCEL® H-D is a product with a higher knitted fabric density and greater thickness. Non-woven forms of resorbable oxidized cellulose are fibrous. OKCEL® F has an extremely high flexibility and the individual layers can be separated. The reinforced fibrous version of OKCEL® S has a reduced weight and increased strength.

Within each form of OKCEL® medical device, several dimensions (variants) are produced so that, with regard to the performed procedure, the physician can choose not only the appropriate form, but also the required dimension. The dimensions are given in the table below.

Table 2: **Forms and dimensions of the OKCEL® medical device**

REF	OKCEL®	REF	OKCEL®
H-T	***Dimensions***	***F***	***Dimensions***
H-T 151	1.5 x 1.5 cm	F 205	2.5 x 5 cm
H-T 501	5 x 1.25 cm	F 575	5 x 7.5 cm
H-T 507	5 x 7 cm	F 510	5 x 10 cm
H-T 510	7 x 10 cm	F 1010	10 x 10 cm
H-T 535	5 x 35 cm	F 1020	10 x 20 cm
H-T 540	10 x 20 cm		
H-D	***Dimensions***	***S***	***Dimensions***
H-D 202	2.5 x 2.5 cm	S 205	2.5 x 5 cm
H-D 209	2.5 x 9 cm	S 505	5 x 5 cm
H-D 575	5 x 7.5 cm	S 510	5 x 10 cm
H-D 710	7 x 10 cm	S 1010	10 x 10 cm
H-D 1420	14 x 20 cm		

How does a medical device work, what ensures its ability to stop bleeding and be resorbed in the body?

When saturated with blood, OKCEL® swells into a gelatinous mass, still maintaining its original structure. The product helps in the formation of a clot by initial denaturation of blood proteins. This leads to local haemostasis (cessation of bleeding at the site of use of the medical device) and control of bleeding.

Oxidized cellulose is a degradable medical device, i.e. it is absorbed in the body over time. It does not need to be removed after the bleeding has stopped (except as defined in the Instructions for Use), so it can be left in the body. A condition for the proper functioning of the device is the use of an amount that is fully saturated with blood.

An additional positive effect to the above cited action is the bacteriostatic and bactericidal properties of the device, which have been demonstrated in vitro.

As a so-called passive haemostat, OKCEL® is suitable for use in patients with intact coagulation. There are no clinical data on the use of the medical device in patients under 12 months of age.

What is the composition of the medical device?

It is an oxidized cellulose, which is prepared from carefully selected cotton by a chemical process – controlled oxidation of cellulose.

How long does a medical device remain in the body?

Absorption of the device usually occurs within 4 weeks of its implantation.

How should you use the *Card* and for how long?

Carry the Card with you, present at all medical examinations min. for 4 weeks. In case of complications that may be related to the device used, consult the physician in the health care facility that implanted the device.

What complications can occur?

Oxidized cellulose swells after saturation with blood and thus there may be a negative effect on soft tissues, which may manifest itself in their narrowing (stenosis – e.g. tubular organs) or paralysis or other damage (nerves).

There have been reports of a stenotic effect when oxidized cellulose has been applied as a wrap during vascular surgery. Although it has not been established that the stenosis was directly related to the use of oxidized cellulose, it is important to be cautious and to avoid applying the material tightly as a wrapping.

Nerve paralysis and damage have been reported when oxidized cellulose was used around, within, or in the proximity of the foramina in bone, spinal root exits from the spine and / or optic nerve, and chiasma opticum (connection and partial crossing of the optic nerves). Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe, when oxidized cellulose was placed in the anterior cranial fossa.

Headache, burning, stinging and sneezing have also been reported with epistaxis (see above) and other rhinological procedures (nasal interventions) as well as stinging where oxidized cellulose was applied on surface wounds (varicose ulcerations, dermal abrasions and donor site).

In addition, a possible effect on prolongation of drainage time in cholecystectomy (surgical removal of the gallbladder) has been reported, and problems with the passage of urine through the urethra after prostatectomy (complete or partial removal of the prostate) have also been reported. Ureteral blockage was noted after kidney resection, which required postoperative catheterization.

When oxidized cellulose was used for epistaxis (stopping bleeding from the nasal vessels), there were occasional reports of "burning," "stinging" and sneezing. This can be attributed to the low pH of the product. Burning has been reported with oxidized cellulose after removal of nasal polyps and after haemorrhoidectomy (removal of haemorrhoids).

Interactions:	Not known.
Overdose / intoxication:	Not known.
Effect on the ability to drive and operate machinery:	Not known.
Use in pregnancy and lactation:	Not known.
What to do in case of complications?	In case of complications that may be related to the device used, consult the physician in the health care facility that implanted the device. The contact for this facility is written on the front of the *Card*. If you are not sure that complications may be associated with the medical device used in your case, consult your general practitioner what to do. Because the medical device is used during clinical intervention, it is also necessary to take into account the complications that are associated with this procedure. Given the influence of a number of factors, the list of potential complications cannot be considered definitive. This document does not replace Instructions for Use of the medical device Okcel®.

OKCEL®

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