Information on the website – section for patients

If our medical device Cellistypt® has been used in a surgical procedure, please pay close attention to the following information. Cellistypt® is a local absorbable haemostat (a device to support the bleeding stop). As it is a degradable medical device, it does not always need to be removed after the bleeding has stopped and can be left in the body. In spite of all the care that Synthesia Nitrocellulose, a.s., as the manufacturer, devotes to this product and that doctors devote 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*.

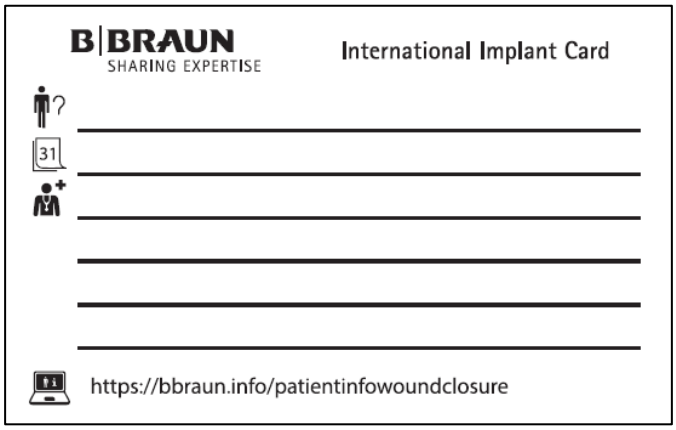
What is an Implant Card and what information does it contain?

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

- on the one hand, information about the medical device – the implant inserted into the patient's body during the clinical procedure;
- on the other hand, information about the patient who received the device and the healthcare facility where the procedure was carried out.

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 inserted into your body, information about the healthcare facility that carried out the procedure, and a link to the medical device manufacturer's website.

The information on the *Implant Card* is assigned to the appropriate symbols, a summary of which can be found in the table below.



The symbol MD on the back of the *Implant Card* indicates that it is a medical device. This symbol is followed by the device's name and the form used, namely Cellistypt®, Cellistypt® D-K, Cellistypt® F or Cellistypt® N-W. Further information on each form is given below.

The symbols with data, 2D code and UDI-DI are also on the back of the card. This information identifies the medical device used. The UDI-DI is a numerical code that is assigned for each catalogue number (REF) – it defines which version (form and size) of the medical device has been used. The forms and versions manufactured are listed by the catalogue number below.

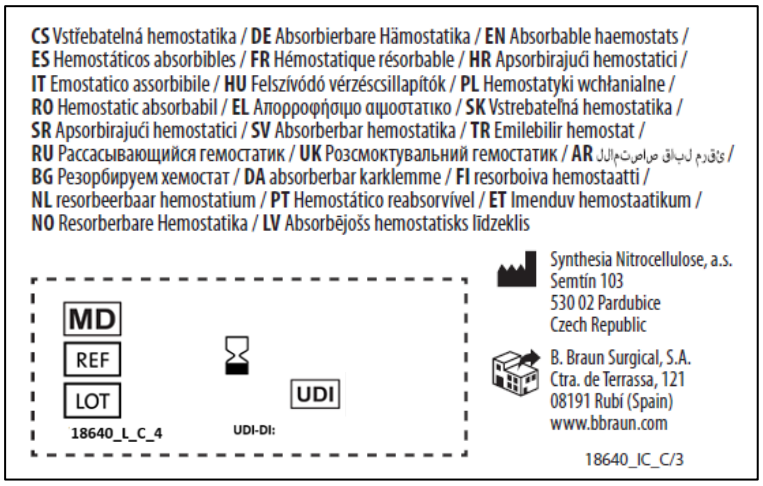


Table 1: Information about the symbols used on the card.

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

What is Cellistypt®, what forms of Cellistypt® are made and how do they differ?
Synthesia Nitrocellulose, a.s. produces Cellistypt® absorbable oxidised cellulose as a sterile absorbable medical device in the form of a knitted fabric (Cellistypt® and Cellistypt® D-K) or a soft, layered material (Cellistypt® F and Cellistypt® N-W). It is produced by the controlled oxidation of cellulose from high-quality cotton fibre.
In defined cases, this medical device serves physicians as an aid during surgical and minimally invasive procedures to control bleeding. **It is what is known as a local haemostat.**

Cellistypt® is a standard-density knitted fabric and Cellistypt® D-K is a thicker product with a higher density of knitted fabric. Non-woven forms of absorbable oxidised cellulose are fibrous. Cellistypt® F is extremely flexible and the individual layers can be separated. The reinforced fibrous version Cellistypt® N-W has a reduced weight and increased strength.

Each form of the Cellistypt® medical device comes in several sizes (variants) so that the physician can choose not only the appropriate form but also the right size for the procedure to be performed. The sizes are given in the table below.

Table 2: Forms and sizes of Cellistypt®

REF	Cellistypt®	REF	Cellistypt®
Cellistypt®	**Sizes**	**Cellistypt® F**	**Sizes**
2080515	1.5 x 1.5 cm	2082025	2.5 x 5 cm
2080501	5 x 1.25 cm	2082075	5 x 7.5 cm
2080508	5 x 7 cm	2082005	5 x 10 cm
2080511	7 x 10 cm	2082010	10 x 10 cm
2080536	5 x 35 cm	2082020	10 x 20 cm
2080541	10 x 20 cm		
Cellistypt® D-K	**Sizes**	**Cellistypt® N-W**	**Sizes**
2081203	2.5 x 2,5 cm	2083250	2.5 x 5 cm
2081209	2.5 x 9 cm		
2081275	5 x 7.5 cm	2083055	5 x 5 cm
2081210	7 x 10 cm	2083510	5 x 10 cm
2081240	14 x 20 cm	2083110	10 x 10 cm

How does the medical device work, how does it stop bleeding and how is it absorbed in the body?

When saturated with blood, Cellistypt® swells into a gelatinous mass that continues to retain its original structure. The formation of a blood clot is supported by the initial denaturation of blood proteins. This leads to local haemostasis (bleeding stops at the site of the medical device) and the control of bleeding.

Oxidised cellulose is a degradable medical device, i.e., it is absorbed by the body over time. It does not need to be removed after bleeding has stopped (except for those exceptions set out in the Instructions for Use), so it can be left in the body. In order for the device to function properly, it must be used in a quantity that fully absorbs the blood.

In addition to the effect described above, it has the added benefit of bacteriostatic and bactericidal properties, which have been demonstrated in vitro.

As a passive haemostatic agent, Cellistypt® is suitable for use in patients with unimpaired coagulation. There are no clinical data on use of the product in patients under 12 months.

What is the medical device made of?

It is oxidised cellulose, which is prepared from carefully selected cotton and treated with a chemical process – the controlled oxidation of cellulose.

How long does the medical device stay in the body?

It is usually absorbed within 4 weeks from implantation.

How should I use the card and for how long?
Carry the card with you and present it at all medical check-ups for at least 4 weeks. If there are complications that may be related to the device used, consult the doctor at the healthcare facility that implanted the device on what to do next.

What complications might arise?
Oxidised cellulose swells when saturated with blood. This can adversely affect soft tissues by narrowing them (stenosis – e.g., tubular organs) or by causing paralysis or other damage (nerves). There have been reports that oxidised cellulose has stenotic effects when used for wrapping in vascular surgery. Although no direct correlation between the incidence of stenosis and the use of oxidised cellulose has been shown, it is important to exercise caution and avoid wrapping this material too tightly.

Paralysis and nerve damage have been reported when oxidised cellulose is applied around the site where nerves enter bone, where spinal roots exit the spine, and/or by the optic nerve and the optic chiasma. Blindness has been reported in association with surgical intervention for left frontal lobe trauma when oxidised cellulose was placed in the anterior cranial fossa.

A possible effect causing a prolongation of the drainage time during cholecystectomy has also been reported, as have difficulties with the passage of urine through the urethra after a prostatectomy. Ureteral blockage after a renal resection has been recorded, requiring postoperative catheterisation.

When oxidised cellulose has been used during epistaxis (stopping a nose bleed), there have been occasional reports of “burning” or “stinging” sensations and sneezing. This can be attributed to the product’s low pH. Burning has been reported when oxidised cellulose is applied after the removal of nasal polyps and after haemorrhoidectomy (the removal of haemorrhoids).

Headaches, burning, stinging and sneezing have also been reported when oxidised cellulose is used for epistaxis (see above) and other rhinological procedures (procedures in the nasal area), as well as stinging when it is applied to the surface of a wound (varicose ulcers, skin abrasions and at the site of skin graft removal).

Interactions:
Not known.

Overdose / intoxication:
Not known.

Effects on ability to drive and operate machinery:
Not known.

Use during pregnancy and breastfeeding:
Not known.

What to do in the event of complications
If complications arise that may be related to the device used, consult a doctor at the healthcare facility that implanted the device on what to do next. The contact details for that facility can be found on the front of the Implant Card.

If you are not sure whether you might be suffering from complications associated with the medical device that has been used on you, consult your GP on what to do. Because the medical device is used in a medical procedure, it is necessary to take into account the complications associated with such procedures. As a multitude of factors may have an effect, the list of potential complications cannot be considered definitive.

This document does not replace the Cellistypt® Medical Device Instructions for Use.