

OKCEL[®]

OFFERING MORE

ABSORBABLE HAEMOSTATS

OXIDIZED
NON-REGENERATED
CELLULOSE



OKCEL® is a **biodegradable, bioresorbable** and **biocompatible**¹ oxidized cellulose based haemostat produced by selective oxidation of **extra-long staple cotton of the finest quality**.

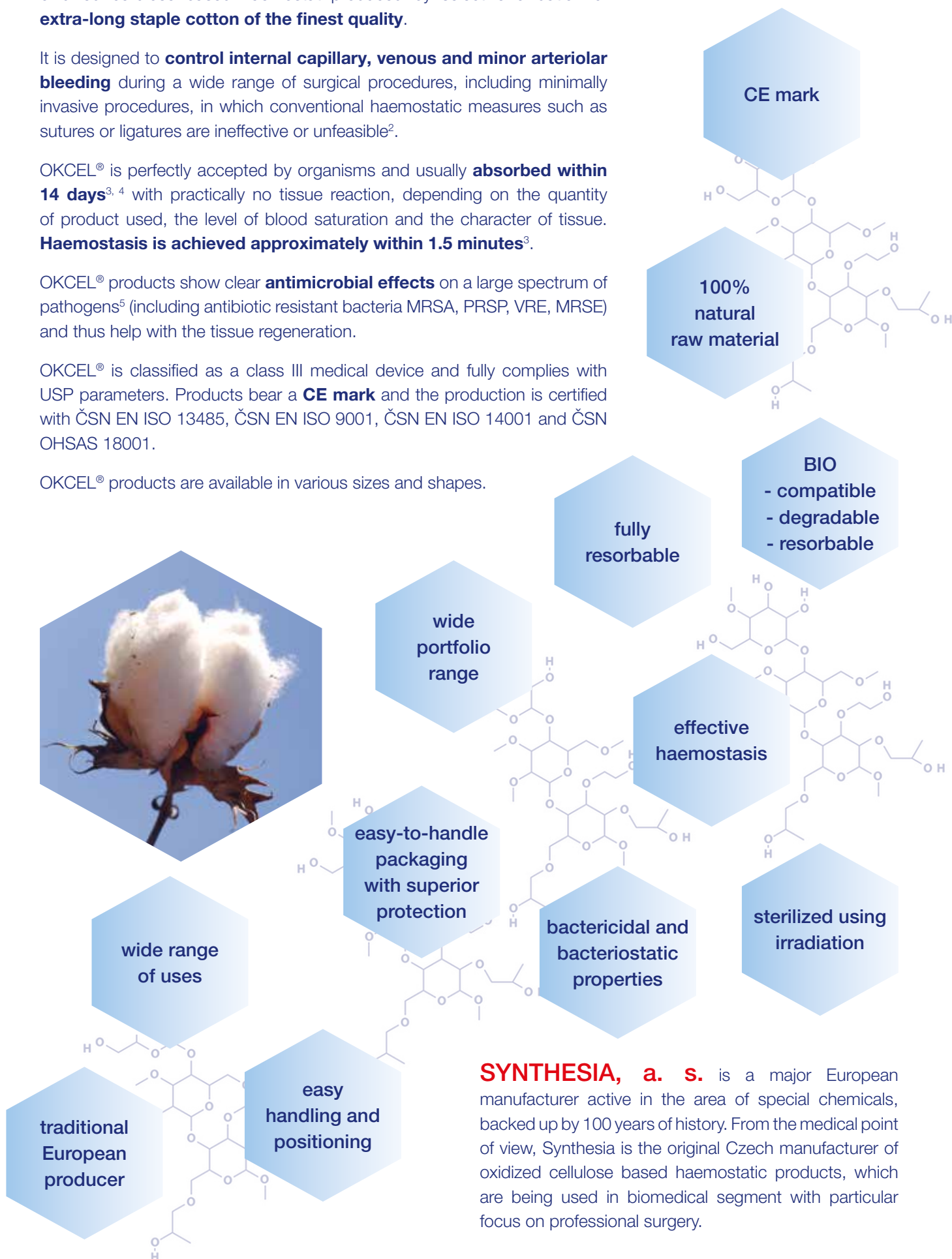
It is designed to **control internal capillary, venous and minor arteriolar bleeding** during a wide range of surgical procedures, including minimally invasive procedures, in which conventional haemostatic measures such as sutures or ligatures are ineffective or unfeasible².

OKCEL® is perfectly accepted by organisms and usually **absorbed within 14 days**^{3, 4} with practically no tissue reaction, depending on the quantity of product used, the level of blood saturation and the character of tissue. **Haemostasis is achieved approximately within 1.5 minutes**³.

OKCEL® products show clear **antimicrobial effects** on a large spectrum of pathogens⁵ (including antibiotic resistant bacteria MRSA, PRSP, VRE, MRSE) and thus help with the tissue regeneration.

OKCEL® is classified as a class III medical device and fully complies with USP parameters. Products bear a **CE mark** and the production is certified with ČSN EN ISO 13485, ČSN EN ISO 9001, ČSN EN ISO 14001 and ČSN OHSAS 18001.

OKCEL® products are available in various sizes and shapes.



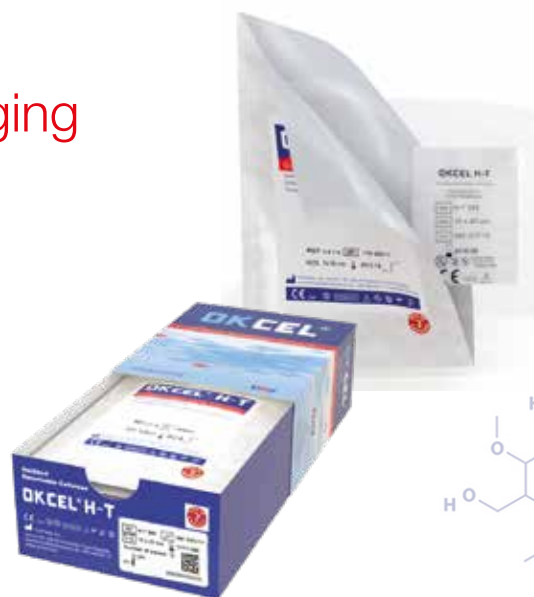
SYNTHESIA, a. s. is a major European manufacturer active in the area of special chemicals, backed up by 100 years of history. From the medical point of view, Synthesia is the original Czech manufacturer of oxidized cellulose based haemostatic products, which are being used in biomedical segment with particular focus on professional surgery.

OKCEL[®] = wide range of uses

| Product type | Description | Handling | Indication |
|------------------------|--|---|--|
| OKCEL [®] H-T | <ul style="list-style-type: none"> knitted regular density textile form | <ul style="list-style-type: none"> can be easily cut without fraying easy (re)positioning at the bleeding site can be rolled does not stick to instruments no memory effect | <ul style="list-style-type: none"> control of capillary, minor venous and minor arteriolar bleeding |
| OKCEL [®] H-D | <ul style="list-style-type: none"> knitted high density textile form higher thickness improved endurance better efficiency | <ul style="list-style-type: none"> can be easily cut without fraying easy (re)positioning at the bleeding site can be rolled does not stick to instruments no memory effect | <ul style="list-style-type: none"> control of higher volume capillary, venous and arteriolar bleeding |
| OKCEL [®] F | <ul style="list-style-type: none"> non-woven cotton wool form multi-layered structure reduced weight extreme absorbency improved adherence extreme flexibility | <ul style="list-style-type: none"> can be easily shaped into a ball or a roll any layer can be easily separated for different intensities of bleeding easy (re)positioning at the bleeding site does not stick to instruments no memory effect | <ul style="list-style-type: none"> control of bleeding over large areas for topical applications to irregularly shaped bleeding sites or difficult to access areas |
| OKCEL [®] S | <ul style="list-style-type: none"> strengthened non-woven cotton wool form higher absorbency against standard form superior handling | <ul style="list-style-type: none"> does not stick to instruments easy (re)positioning at the bleeding site easy application through a laparoscopic trocar no memory effect | <ul style="list-style-type: none"> control of capillary, venous and arteriolar bleeding suitable for laparoscopic use |

OKCEL[®] = easy-to-handle packaging

- compliance with the highest standards for medical device packaging
- easy handling and opening (a peel-effect on both primary and secondary pouches)
- superior protection over a whole shelf life period and outstanding resistance to microbial penetration (even the primary pouch is sealed)
- minimum risk of package failure
- all the relevant information for users clearly provided
- practical suture box consisting of sealed primary and secondary pouches, IFU and triple-stickers for better product traceability



OKCEL[®] = proven antimicrobial properties



The bactericidal and bacteriostatic properties of OKCEL[®] are another positive effect that the use of our products brings to topical haemostasis. The antimicrobial effect of OKCEL[®] products on a large spectrum of pathogens is caused by the formation of low pH environment around the wound. The lower pH levels inhibit the growth and multiplication of Gram-negative and Gram-positive bacteria, including both aerobic and anaerobic strains. This **efficiency has been confirmed against 36 strains, including antibiotic-resistant bacteria** (MRSA, PRSP, VRE, MRSE)⁵.

OKCEL[®] = offering more

The most widely used biodegradable haemostatic agent is oxidized regenerated cellulose (ORC). OKCEL[®] as non-regenerated oxidized cellulose (ONRC) has very similar characteristics and practically the same indication but may vary in some parameters important for its clinical use.



Premium raw material

OKCEL[®] is produced from **pure extra-long staple (ELS) cotton of the highest quality** which is only mechanically pre-treated and bleached, while ORC is made of viscose obtained by chemical modification of cellulose.



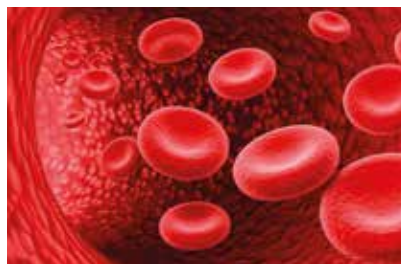
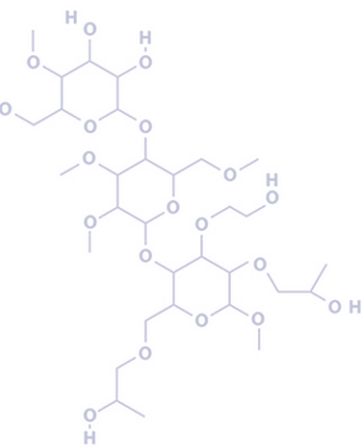
Easier re-positioning with no memory effect

Excellent shape stability and slower gelatination of ONRC allows the haemostatic material to be further manipulated and relocated even after placement in a bleeding site. This **significantly simplifies material handling during surgical procedures**.⁶



Equivalent bactericidal effect

Despite a slight difference in the acidity of ORC and ONRC, **no difference in bactericidal effect** was observed.⁷



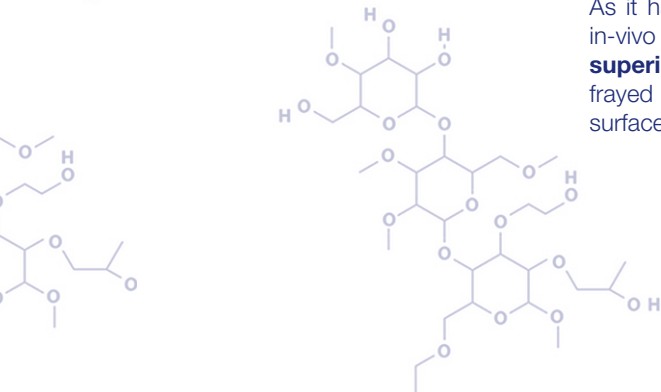
Superior haemostasis

As it has been proven in comparative in-vivo models, ONRC provides **superior haemostasis** thanks to its frayed fibres which create a greater surface area.⁷



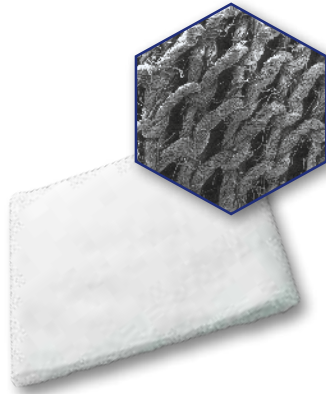
Superior bio-resorbability/bio-degradability

The in-vitro bioresorbability simulation tests demonstrated **better disintegration of ONRC** against ORC which created a compact clot of material. This could in-vivo cause a foreign-body granuloma imitating different pathological conditions which might complicate the post-surgical imaging.⁶



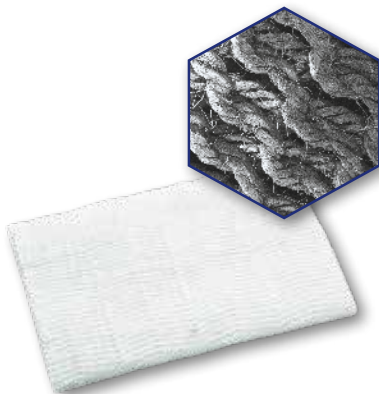
OKCEL® = wide portfolio range

BASIC PRODUCT LINE



OKCEL® H-T original textile form of oxidized cellulose

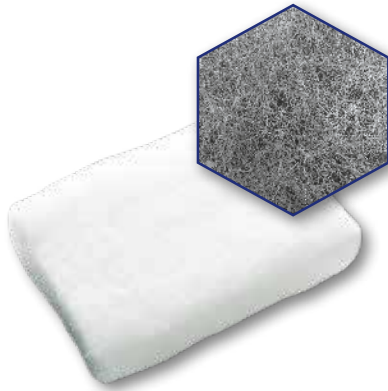
| Item | Format size | Packaging [pcs / sales unit] |
|---------------|--------------|------------------------------|
| OKCEL H-T 101 | 1.5 × 1.5 cm | 100 |
| OKCEL H-T 151 | 1.5 × 1.5 cm | 40 |
| OKCEL H-T 501 | 5 × 1.25 cm | 15 |
| OKCEL H-T 507 | 5 × 7 cm | 15 |
| OKCEL H-T 510 | 7 × 10 cm | 15 |
| OKCEL H-T 535 | 5 × 35 cm | 10 |
| OKCEL H-T 540 | 10 × 20 cm | 10 |



OKCEL® H-D heavy duty textile form of oxidized cellulose

| Item | Format size | Packaging [pcs / sales unit] |
|----------------|--------------|------------------------------|
| OKCEL H-D 202 | 2.5 × 2.5 cm | 15 |
| OKCEL H-D 209 | 2.5 × 9 cm | 15 |
| OKCEL H-D 575 | 5 × 7.5 cm | 10 |
| OKCEL H-D 710 | 7 × 10 cm | 10 |
| OKCEL H-D 1420 | 14 × 20 cm | 10 |

ADVANCED PRODUCT LINE



OKCEL® F fibrillar cotton wool form of oxidized cellulose

| Item | Format size | Packaging [pcs / sales unit] |
|--------------|-------------|------------------------------|
| OKCEL F 205 | 2.5 × 5 cm | 10 |
| OKCEL F 575 | 5 × 7.5 cm | 10 |
| OKCEL F 510 | 5 × 10 cm | 10 |
| OKCEL F 1010 | 10 × 10 cm | 10 |
| OKCEL F 1020 | 10 × 20 cm | 10 |



OKCEL® S strengthened cotton wool form of oxidized cellulose

| Item | Format size | Packaging [pcs / sales unit] |
|--------------|-------------|---------------------------------|
| OKCEL S 205 | 2.5 × 5 cm | 10 Ideal for laparoscopy |
| OKCEL S 505 | 5 × 5 cm | 10 Ideal for laparoscopy |
| OKCEL S 510 | 5 × 10 cm | 10 |
| OKCEL S 1010 | 10 × 10 cm | 10 |

**NEW
INNOVATION**

Distributed by

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References:

1. Based on biocompatibility testing of OKCEL® products in accordance with EN ISO 10993. Data on file: 18640-033. **2.** Based on OKCEL® instructions for use. Data on file: 18640-033. **3.** Jindřich Lahovský, MD. Evaluation of efficacy and safety of medical devices series OKCEL®. Study Report Ref. No AP-SY-1501. Data on file: 18640 – 033. **4.** Jindřich Lahovský, MD. Evaluation of efficacy and safety of the medical device OKCEL® S. Study Report Ref. No AP-SY-1701. Data on file: 18640 – 033. **5.** Ing. Iveta Brožková, Ph. D. Department of Biological and Biochemical Sciences at the Faculty of Chemical Technology, University of Pardubice. Final report on testing the antimicrobial activity of the product OKCEL®. Data on file: 18640 - 034. **6.** Jindřich Lahovský, MD. Závěrečná zpráva laboratorního vyhodnocení vlastností hemostatik na bázi oxidované regenerované a neregenerované celulózy. Study Report Ref. No. AP-SY-1901. Data on file: 18640 – 034. **7.** K. M. Lewis, DVM, D. Spazierer, PhD, M. D. Urban, HT (ASCP), L. Lin, PhD, H. Redl, PhD, A. Goppelt, PhD: Comparison of regenerated and non-regenerated oxidized cellulose hemostatic agents. [on-line]. Eur Surg. 2013; 45(4): 213–220. Available on: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3739866/>

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.
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