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Characteristics of Cellistyp[®]

The topical absorbable hemostats Cellistyp[®] are medical devices based on oxidized cellulose, intended for use during surgical and minimally invasive procedures to assist in control of capillary, venous and small arterial bleeding when ligation or other conventional methods of bleeding control are impractical or ineffective.

Oxidized Resorbable Cellulose (Cellistyp[®]) is manufactured in different forms and dimensions which make possible adequate choice for particular patient, particular clinical situation respectively.

The medical device is degradable – the extraction after achieving haemostatic effect is not necessary (but it is possible), except of defined cases to avoid non-desired side-effects associated with Oxidized Resorbable Cellulose during implantation period.

The adjustment of the device position to achieve optimal clinical effect after its placement is possible.

Oxidized cellulose (OC) is generated by selective oxidation of high quality cotton – purely natural material originating from blossoms of cotton plants. Natural cellulose fibers are still recognizable as being from a part of the original plant – the material is only pretreated before processing. Using textile machines, cotton fibers are physically connected, creating yarn / wool ready for oxidation. Product family of topical absorbable hemostats Cellistyp[®] in knitted form consists of Cellistyp[®] and Cellistyp[®] D-K, in cotton wool form consists of Cellistyp[®] F and Cellistyp[®] N-W. The forms differ in physical and application properties.

Cellistyp[®]

Cellistyp[®] D-K

Cellistyp[®] F

Cellistyp[®] N-W

Cellistyp[®] H-T

Knitted, regular density version of the absorbable hemostatic material, used for control of the capillary bleeding, as well as minor venous or arteriolar diffuse bleeding.

Cellistyp[®] D-K

Knitted, high density version of the absorbable hemostatic material with higher thickness and improved efficiency, used for control of higher volume capillary and venous or arteriolar bleeding.

Cellistyp[®] F

Non-woven, multilayer fibrillar version of the absorbable hemostatic material extremely high flexibility, used to control of hemostasis over a large area, for surface applications on irregularly shaped bleeding sites or in areas that are difficult to access.

It can be easily placed on the bleeding site using forceps. Any amount of Cellistyp F can be easily separated in such a way that the fibres continue to hold together without uncontrolled release into the operative site.

Cellistyp[®] N-W

The non-woven reinforced fibrous version Cellistyp[®] N-W with reduced weight and increased strength is used to control capillary, venous and minor arteriolar diffuse bleeding and it may be more suitable for endoscopic use. The material maintains its original structure even when saturated with blood and can be easily manipulated in the bleeding site with no signs of disintegration.

The products are individually packed into double-pouch packaging and sterilized by γ -irradiation.

Technical specification and chemical properties – oxidized cellulose, oxidized regenerated cellulose and Cellistyp[®]

	Unit	USP OC	USP ORC*	Cellistyp [®]
Cellulose	-	Natural/Plant	Regenerated	Cotton
Identification	-	Corresponds	Corresponds	Corresponds
Loss on drying	wt%	Max. 15	Max. 15	Max. 15
Residue on ignition	wt%	Max. 0.15	Max. 0.15	Max. 0.15
Nitrogen content	wt%	Max. 0.5	Max. 0.5	Max. 0.5
Formaldehyde	wt%	Max. 0.5	Max. 0.5	Max. 0.5
Assay of –COOH groups	wt%	16 – 24	18 – 24	16 – 24
pH value in 1% extract	-	-	-	2.2-4.5

*Note: Oxidized regenerated cellulose (ORC) is formed by oxidation of viscose resp. chemically regenerated cellulose (also known as artificial silk). Natural cellulose is in this case the feedstock, which is chemically converted via carbon disulfide in soluble form, producing long, lustrous fibers of the same diameter throughout its length. Further processing of yarn and the principle of oxidation is the same as in the case of OC. OC and ORC are two separate items of United States Pharmacopeia Convention (USP).

Physical and application properties

	Unit	Cellistyp [®]	Cellistyp [®] D-K	Cellistyp [®] F	Cellistyp [®] N-W
Textile structure	-	Knitted, flexible		Non-woven	
Color	-	White to yellowish			
Area weight ⁽¹⁾ – limit	<i>g/m²</i>	85-135	200-400	200-400	140-240
typically	<i>g/m²</i>	110-125	230-270	250-290	170-210
Adherence ⁽²⁾	-	Corresponds	Corresponds	-	Corresponds
Sinking time ⁽³⁾ – limit (max)	<i>s</i>	15			
typically	<i>s</i>	1	1	2	2
Hemostasis time ⁽⁴⁾ – on average	<i>min</i>	1.5			
Water absorption ⁽⁵⁾ typically	<i>g H₂O/cm²</i>	0.05-0.06	0.08-0.09	0.49-0.56	0.32-0.39
Bioresorbability ⁽⁶⁾ – limit (max.)	<i>days</i>	14			
typically	<i>days</i>	7-8	7-8	4	4
γ-sterilization	<i>kGy</i>	18 - 32			

Note: Typically values usually achievable during production (Cellistyp, Cellistyp D-K, Cellistyp F) or stability study (Cellistyp N-W) are evaluated in the Report no. 08/2020, issued by Technical development.

- (1) Test of oxycellulose area weight performed according to API 11/1430/21
- (2) Test of adherence oxycellulose to human skin after water absorption (API 11/1430/25)
- (3) Test of sinking time in seconds (API 11/1430/24)
- (4) Report AP-SY-1501 Evaluation of efficacy and safety of medical devices series OKCEL and Report AP-SY-1701 Evaluation of efficacy and safety of medical device OKCEL S
- (5) Test of oxycellulose water absorption performed according to API 11/1430/22
- (6) Test according to API 11/1430/18 Bioresorbability in peptone solution (QC laboratory Oxycellulose)

Final product sizes

		Cellistyp [®]	Cellistyp [®] D-K	Cellistyp [®] F	Cellistyp [®] N-W
Sizes	cm x cm	1.5 x 1.5	2.5 x 2.5	2.5 x 5	2.5 x 5
		5 x 1.25	2.5 x 9	5 x 7.5	5 x 5
		5 x 7	5 x 7.5	5 x 10	5 x 10
		7 x 10	7 x 10	10 x 10	10 x 10
		5 x 35	14 x 20	10 x 20	
		10 x 20			

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