



A completely absorbable haemostatic gelatine sponge consisting of purified neutral pharmaceutical gelatine foam of uniform porosity

General Characteristics

CuraSpon® is a gelatine sponge produced from pharmaceutical gelatine.
Presentation in plates (e.g. standard), thin sheets (special, film), cylinder (tampon), cubes (cube, dental) and powder.

- Gelatine of porcine origin
- Haemostasis in 2 – 4 minutes
- Completely absorbed within 2 - 4 weeks
- Liquefies in 2 - 5 days in contact with mucosa
- Can be used dry or impregnated
- Compatible with pharmaceuticals
- Absorbs at least 35 times its own weight in blood and fluids
- Does not stick to instruments
- Possibility to introduce in endoscopic procedures or trocar
- 100% biodegradable
- Available in sponge and powder form.

Indications

General indications: **CuraSpon®** is used during and after surgical procedures to achieve local haemostasis by tamponade effect.

It is intended for the use as an absorbable haemostat in various fields of surgery.
Provides haemostasis generally within 2 - 4 minutes after application.
Liquefies in 2-5 days when applied to mucosa.
Absorbs in 4-6 weeks when implanted in the organism, depending on method of use and site of implantation.
Because of its neutral character and nature, it may be used as a carrier for any drug

Biocompatibility

In conformance with Harmonized Standard NEN ISO 10993-1

Packaging

Individually packaged in sterile blister or container.
Single or double packaged according to the overview on page 2 of this Datasheet.

Method of sterilization

Gamma irradiation in accordance with Harmonized Standard EN ISO 11137-1

Shelf life

5 years

Manufacturer

CuraMedical B.V. – Industrieweg 6B – 1566 JP ASSENDELFT – The Netherlands – www.curamedical.com

Quality Management System - Scope: design, manufacturing and distribution of sterile absorbable haemostats – CE 0483

The MDC audit has proven that the Quality Management System meets all requirements for the standard EN ISO 13485 Medical Devices – Quality Management Systems – requirements for regulatory purposes (EN ISO 13485:2016 + AC:2018 – + A11:2021 ISO 13485:2016). Certificate N° D1169400038 of May 29th 2024 – Valid until May 28th 2027.

Quality System for design, manufacture and final inspection – CE 0483

The MDC audit has proven that the Quality System meets all requirements according to Annex II – section 3 of the council directive 93/42/EEC of 14 June 1993 concerning medical devices.

Certificate N° D1169400028 of April 30th 2020 – Valid until May 26th 2024. Surveillance in accordance with Annex II, section 5.

Notified Body Confirmation letter is issued D1169400035 dated 24-04-2024 that confirms the grace period and extends our certificates remaining valid until 31 December 2027.

CE Marking: Class III according to Annex IX rules 8 and 17 – CE 0483

The examination of the design dossier of CuraSpon® by MDC has proven that according to report N° P20-01305-182815 of the file review the design meets the requirements according to Annex II – section 4 of the council directive 93/42/EEC of 14 June 1993 concerning medical devices. Certificate N° D1169400031 of May 18th 2021 – Valid until May 26th 2024. Notified Body Confirmation letter is issued D1169400035 dated 24-04-2024 that confirms the grace period and extends our certificates remaining valid until 31 December 2027.

Sterilization site

Synergy Health AST, Ede – Morsestraat 3 – 6716 AH EDE – The Netherlands, Certification EN ISO 13485:2016 (BSI).

CuraSpon® haemostatic gelatine sponges are available in accordance with the following table.

CuraMedical Article nr.	Description	Dimensions	Primary packaging	Secondary packaging	pcs per box
CS-010	Standard	80 x 50 x 10 mm	Hard Blister	Soft Blister	20
CS-030 ¹	Streifen	80 x 40 x 10 mm	Hard Blister	Soft Blister	20
CS-050 ¹	Size 16	80 x 20 x 10 mm	Hard Blister	Soft Blister	20
CS-060	Size 12-7	60 x 20 x 7 mm	Hard Blister	Soft Blister	20
CS-070	Size 13-5	51 x 13 x 10 mm	Hard Blister	Soft Blister	20
CS-110 ³	Special	80 x 50 x 1 mm	Hard Blister	Soft Blister	15
CS-110	Special	80 x 50 x 1 mm	Hard Blister	Soft Blister	12
CS-111 ³	Special	70 x 50 x 1 mm	Hard Blister	Soft Blister	15
CS-111	Special	70 x 50 x 1 mm	Hard Blister	Soft Blister	12
CS-130 ²	Sheet	80 x 50 x 3 mm	Hard Blister	Soft Blister	20
CS-210 ³	Tampon	ø 30 x 80 mm	Hard Blister	Soft Blister	15
CS-210	Tampon	ø 30 x 80 mm	Hard Blister	Soft Blister	12
CS-260	Powder Paste	1 gram	PP Container	Soft Blister	4
CS-310	Cube	10 x 10 x 10 mm	Hard Blister	PE zip-bag	50
CS-320 ²	Cube XL	15 x 15 x 10 mm	Hard Blister	-	30
CS-330	Dental 60	10 x 10 x 10 mm	PP Container	-	2x30
CS-420	Dial 2-2	20 x 20 x 10 mm	Hard Blister	-	30
CS-442 ²	Dial 4-2	40 x 10 x 10 mm	Hard Blister	Soft Blister	5x2
CS-452 ²	Nasal Tampon	50 x 10 x 10 mm	Hard Blister	Soft Blister	5x2
CS-465	Strip	40 x 10 x 10 mm	Hard Blister	Soft Blister	4
CS-610 ³	Size 100	125 x 80 x 10 mm	Soft Blister	Soft Blister	15

¹ Only available for German market

² Only available on special request in high volumes

³ This refers to the legacy packaging (15 pcs). This version will gradually be replaced by the new state-of-the-art packaging (12 pcs) under the same REF. Both GTINs will remain temporarily available during the transition period.

CS-610	Size 100	125 x 80 x 10 mm	Soft Blister	Soft Blister	12
CS-950 ³	Film	200 x 70 x 0,5 mm	Hard Blister	Soft Blister	15
CS-950	Film	200 x 70 x 0,5 mm	Hard Blister	Soft Blister	12

