

**CELLACAST® Xtra**

REF 139850 – 139861; 139863 – 139865; 139867 - 139869

June 2021

1. Composition of the product

CELLACAST® Xtra consists of:

- knitted fibreglass fabric
- polyurethane resin containing a "detackifier"

The product data sheet covers the following items:

REF	Product description	Feature	Colour
139850	CELLACAST® Xtra	2,5 cm x 1,8 m	cream-coloured
139851	CELLACAST® Xtra	5 cm x 3,6 m	cream-coloured
139852	CELLACAST® Xtra	7,5 cm x 3,6 m	cream-coloured
139853	CELLACAST® Xtra	10 cm x 3,6 m	cream-coloured
139854	CELLACAST® Xtra	12,5 cm x 3,6 m	cream-coloured
139855	CELLACAST® Xtra	5 cm x 3,6 m	blue
139856	CELLACAST® Xtra	7,5 cm x 3,6 m	blue
139857	CELLACAST® Xtra	10 cm x 3,6 m	blue
139858	CELLACAST® Xtra	12,5 cm x 3,6 m	blue
139859	CELLACAST® Xtra	5 cm x 3,6 m	black
139860	CELLACAST® Xtra	7,5 cm x 3,6 m	black
139861	CELLACAST® Xtra	10 cm x 3,6 m	black
139863	CELLACAST® Xtra	5 cm x 3,6 m	red
139864	CELLACAST® Xtra	7,5 cm x 3,6 m	red
139865	CELLACAST® Xtra	10 cm x 3,6 m	red
139867	CELLACAST® Xtra	5 cm x 3,6 cm	purple
139868	CELLACAST® Xtra	7,5 cm x 3,6 cm	purple
139869	CELLACAST® Xtra	10 cm x 3,6 cm	purple

2. Packaging, structure and composition

2.1 Unit Container

1 piece = 1 tubular bag produced from polyester, aluminum and polyethylene; polypropylene core

2.2 Shelf Container

10 pieces = 1 folding box (cellulose)
instructions for use (paper)

2.3 Transit Container

40 pieces = 1 corrugated cardboard box (cellulose)

3. Manufacture

CELLACAST® Xtra is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

4. Description

Close-knitted fiberglass fabric impregnated with polyurethane resin and manufactured to immersion ready CELLACAST® Xtra casting tape. The CELLACAST® Xtra is available in cream-coloured, purple, blue, red and black. The casting tape is individually sealed in tubular bags.

5. Properties

The largely tack-free and widthwise extensible material simplifies the application and the fashioning of the casting material. Casts made with only a few circular turns of CELLACAST® Xtra possess high stability for extraordinary low weight. The CELLACAST® Xtra casts are X-ray transparent, permeable to air and, when fully set, water resistant.

6. Intended purpose

CELLACAST® Xtra is intended to be used for immobilization following fractures, surgery, or orthopaedic corrections; treatment of joint and bone conditions.

7. Medical device classification

CELLACAST® Xtra is a medical device of Class I in terms of Rule 1. (Council Directive 93/42/EEC covering medical devices, Annex IX)

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

CELLACAST® Xtra must not come into direct contact with the skin. Wearing gloves while applying CELLACAST® Xtra is mandatory for the person applying the casting tape to avoid contact between the skin and the uncured casting material.

The starting materials used in the manufacture of CELLACAST® Xtra are safe if the product is used appropriately and for the purposes intended.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device CELLACAST® Xtra and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Requirements regarding the safety/harmlessness of the constituents

There is currently no information available on critical constituents.

10. Stability

Stored appropriately- at temperatures not exceeding 30°C - CELLACAST® Xtra has a shelf life of 2 years.

11. Disposal

Prior to the disposal of unused CELLACAST® Xtra casting tape, the package must be opened to allow the tape to dry out.

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse. Packaging materials must also be disposed of in compliance with applicable national requirements.

12. Legal manufacturer


The following legal manufacturer hereby confirms the accuracy of the information provided in this product data sheet:

Legal manufacturer:

**T&L (Jiaxing) Co., Ltd.
4F, No. 159-1, Chenggong Road,
Huimin Street, Jiashan, Jiaxing
Zhejiang 314100
CHINA**

Distributor:

**Lohmann & Rauscher Internat
GmbH & Co. KG
Westerwalstraße 4
56579 Rengsdorf
Germany**

Aug. 11. 2021. 
Date/Signature


Date/Signature