

## Product Data Sheet

<b>1.0 Name of the product</b>	Delta-Cast <sup>®</sup> Elite
<b>2.0 Product description</b>	
<b>2.1 Description</b>	Delta-Cast <sup>®</sup> Elite is a non-fiberglass casting tape with elastic, knitted polyester substrate. The product consists of a knitted substrate impregnated with a polyurethane resin.
<b>2.2 Intended purpose</b>	Delta-Cast <sup>®</sup> Elite casting tape is intended for external rigid immobilization through casting and/or splinting procedures. The purposes for external rigid immobilization include: <ul style="list-style-type: none"> <li>• Immobilization of bone fractures</li> <li>• Treatment of soft tissue and joint injuries</li> <li>• Immobilization within treatments for correction or prevention of anatomical deformities</li> <li>• Specialized orthotic and prosthetic applications</li> <li>• Total contact casting used for off-loading purposes</li> </ul> Intended Users are Health Care Professionals.
<b>2.3 Instructions for use</b>	Yes
<b>2.4 Warnings and precautions for use</b>	<ul style="list-style-type: none"> <li>- Any wound must be dressed prior to application of the splint</li> <li>- Skin contact with uncured polymer must be avoided, in case of accidental contact swabbing lightly with alcohol or acetone may help remove resin from skin</li> <li>- Instruct patient that cast/splint feels warm during setting</li> <li>- Excessive exotherm can cause burns. The following are factors that can increase heat: <ul style="list-style-type: none"> <li>• Dipping in water above 25°C (77°F)</li> <li>• Too many squeezes in water when activating</li> <li>• Expressing too much water from the tape</li> <li>• Excessive layering</li> <li>• Restricting air flow, for example by: <ul style="list-style-type: none"> <li>Using elastic bandages</li> <li>Covering the cast with a blanket</li> </ul> </li> </ul> </li> <li>- Apply extra padding if required, e.g. on bony prominences</li> <li>- Instruct the patient: <ul style="list-style-type: none"> <li>• Caution against activities too vigorous for their injury or for the integrity of the cast</li> <li>• Immersion in water is allowed only when approval from a qualified medical professional and when waterproof padding (Delta-Dry<sup>®</sup>) is used. Blot with towel to remove excess moisture.</li> <li>• Use mild, non-irritating soap around casted area and avoid getting dirt, sand, or other foreign objects under the cast, as they may cause skin irritation</li> <li>• Do not insert foreign objects under the cast</li> </ul> </li> <li>- Do not use if the package is already open or damaged Product should be soft and pliant all over</li> <li>• Do not reuse the device</li> </ul>
<b>2.5 Contraindications</b>	None known

<b>2.6 Transport Precautions</b>	Not applicable
<b>2.7 Duration of application Period of use</b>	Days up to several weeks as determined by healthcare practitioner
<b>2.8 Information on reusable/ washable products</b>	Single Use
<b>2.9 Composition</b>	<b>Description</b>
	Methylenediphenyl diisocyanate
	4,4' Diphenylmethane diisocyanate-polypropylene glycol polymer
	Total free isocyanate functions
	2,2' Dimorpholinyl diethyl ether
	<b>% [w/w]</b>
	1-10%
	25-40%
	<8%
	1-3%
	40-50%

**2.10 Product range**

Size	Color	Per folding box	Per shipper	Product code		
5cm x 3.6m	Red	10	1	72275-00		
7.5cm x 3.6m				72275-01		
10cm x 3.6m				72275-02		
5cm x 3.6m	Deep Blue			72276-00		
7.5cm x 3.6m				72276-01		
10cm x 3.6m				72276-02		
12.5cm x 3.6m	Purple			72276-03		
5cm x 3.6m				72277-00		
7.5cm x 3.6m				72277-01		
10cm x 3.6m	Black			72277-02		
5cm x 3.6m				72278-00		
7.5cm x 3.6m				72278-01		
10cm x 3.6m	White			72278-02		
5cm x 3.6m				72279-00		
7.5cm x 3.6m				72279-01		
10cm x 3.6m		72279-02				
12.5cm x 3.6m		72279-03				
2.5cm x 1.8m		72279-04				
5cm x 3.6m		1	10	72279-10		
7.5cm x 3.6m				72279-11		
10cm x 3.6m				72279-12		
12.5cm x 3.6m				72279-13		
2.5cm x 1.8m				72279-14		
5cm x 3.6m				10	1	73453-00
7.5cm x 3.6m						73453-01
10cm x 3.6m		73453-02				
5cm x 3.6m		73454-00				
	Light Blue					
	Green					

Size	Color	Per folding box	Per shipper	Product code
7.5cm x 3.6m	Green	10	1	73454-01
10cm x 3.6m				73454-02
5cm x 3.6m	Pink			73455-00
7.5cm x 3.6m				73455-01
10cm x 3.6m	73455-02			
5cm x 3.6m	Neon Orange			73456-00
7.5cm x 3.6m				73456-01
10cm x 3.6m	73456-02			
5cm x 3.6m	Multi			73457-00
7.5cm x 3.6m				73457-01
10cm x 3.6m	73457-02			
10cm x 38cm	White			74545-03
10cm x 90cm				74545-04
12.5cm x 90cm				74545-05
7.5cm x 76cm				74545-06
5cm x 20cm				74545-07
7.5cm x 20cm		74545-08		
7.5cm x 38cm		74545-09		

<b>2.11 Sizing Chart</b>	Not applicable
<b>2.12 Storage conditions</b>	Between 15-25°C (59-77°F) Short periods of time at elevated temperatures are tolerated, there is no need for climatized transport.
<b>2.13 Shelf life/ Storage time</b>	Product has a two (2) year shelf life
<b>2.14 Sterilization</b>	Non-sterile

### 3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link [www.essity.com/gss](http://www.essity.com/gss)

Deviations are covered in 3.1 Components.

### 3.1 Components

Raw materials used in product formulation

Substance	Included in formulation
natural rubber Latex	No
Lanolin and its derivatives	No
Colophony	No
Colophony derivatives	No
Bisphenol A (BPA)	No
Polyvinylchloride (PVC)	No
Methylmethacrylate	No
Butylacrylate	No
Microplastics (<5 mm)	No
Nanoparticles	No
Fragrance/parfum	No
Antibiotics	No
Triclosan	No
Chlorhexidine	No
Polyhexanide	No

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Partly in shipper case

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch BSN medical Inc. US cannot provide proof of absence.

## History

Version / Date	Page / Item	Description of Change
01 / 06.05.2021	All	Set up new document