

Product Data Sheet

1.0 Name of the product	Dynacast® Prelude
2.0 Product description	
2.1 Description	Dynacast® Prelude is a pre-padded synthetic splint system. The product is a knitted fiberglass single layer substrate impregnated with a polyurethane resin and enclosed within a polypropylene padding material.
2.2 Intended purpose	Dynacast® Prelude splints and pre-cut splints are intended for external rigid immobilization through splinting procedures. The purposes for external rigid immobilization include: <ul style="list-style-type: none"> • Immobilization of bone fractures • Treatment of soft tissue and joint injuries Intended Users are Health Care Professionals.
2.3 Instructions for use	Yes
2.4 Warnings and precautions for use	<ul style="list-style-type: none"> • Any wound must be dressed prior to application of the splint • Skin contact with uncured polymer must be avoided. Wear gloves and make sure the padding completely covers the splint before applying on patient • Use water not warmer than room temperature to avoid burns during setting reaction • The setting reaction is exothermic, instruct the patient that the splint might feel warm during setting • Apply extra padding if required, e.g. on bony prominences • Do not use if the package is already open or damaged • Do not reuse the device
2.5 Contraindications	Not known
2.6 Transport Precautions	Not applicable
2.7 Duration of application	The products can remain on the intact skin and on the surgical dressing until end of the treatment (typically 1-2 weeks).
2.8 Information on reusable/ washable products	A healthcare professional must confirm that the splint may be removed for cleaning. The cured splint can be cleaned by hand washing with mild detergent. Before re-application the splint must be completely dried to avoid skin macerations. Proper drying techniques are wiping with a towel first and then using a hairdryer on cold setting for complete drying.
2.9 Composition	<u>Synthetic splint:</u> Fiberglass, 4,4' Diphenylmethane diisocyanate-polypropylene glycol polymer, Methylene-diphenyl diisocyanate, 2,2' Dimorpholinyl-diethyl ether <u>Padding:</u> 100% Polypropylene

	Size/ Color	Per folding box	Per shipper	Product code	
	2.10 Product range	7.5CM X 30CM	1 PRECUT	20	4722200
7.5CM X 40CM		1 PRECUT	20	4722300	
10CM X 30CM		1 PRECUT	20	4722400	
10CM X 40CM		1 PRECUT	20	4722500	
10CM X 76CM		1 PRECUT	16	4722600	
12.5CM X 65CM		1 PRECUT	16	4722700	
12.5CM X 76CM		1 PRECUT	16	4723500	
10CM X 4.6M		1 ROLL	2	7141500	
12.5CM X 4.6M		1 ROLL	2	7141600	
15CM X 4.6M		1 ROLL	2	7141700	
2.5CM X 4.6M		1 ROLL	2	7141800	
20C X 2.3M		1 ROLL	2	7141900	
7.5CM X 30CM*		1 PRECUT	1	7141909	
10CM X 38CM*		1 PRECUT	1	7141910	
10CM X 76CM*		1 PRECUT	1	7141911	
12.5CM X 76CM*		1 PRECUT	1	7141912	
7.5CM X 30CM*		1 PRECUT	5	7141915	
10CM X 38CM*		1 PRECUT	5	7141916	
10CM X 76CM*		1 PRECUT	5	7141917	
12.5CM X 76CM *		1 PRECUT	5	7141918	
5CM X 4.6M		1 ROLL	2	7142000	
7.5CM X 4.6M		1 ROLL	2	7142100	
5CM X 25CM		1 PRECUT	20	7286900	
15CM X 76CM		1 PRECUT	5	7341800	
		* France only			
2.11 Sizing Chart		Not applicable			
2.12 Storage conditions		Between 15 and 25°C (59-77°F) Short periods of time elevated temperatures are tolerated, there is no need for climatized transport			
2.13 Shelf life/ Storage time		3 years			
2.14 Sterilization	Not applicable				

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

Deviations are covered in 3.1 Components.

3.1 Components [R&D & Packaging]

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	No

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 cannot provide proof of absence.

History

Version / Date	Page / Item	Description of Change
01 / 25.02.2021	All	Set up new document