

EN Instructions for use

- **Delta-Lite® Conformable** Fiberglass Casting Tape with elastic, knitted fiberglass substrate, available in white and colors.
- **Delta-Lite® Plus** Fiberglass Casting Tape with knitted fiberglass substrate, available in white and colors.
- **Delta-Lite®** Fiberglass reinforcement strips with knitted fiberglass substrate, available in white only. Strips are for reinforcing synthetic cast.
- **Delta-Cast® Conformable** Non-fiberglass casting tape with elastic, knitted polyester substrate, available in white and colors.
- **Delta-Cast® Elite** Non-fiberglass casting tape with elastic, knitted polyester substrate, available in white and colors.
- **Delta-Cast® Prints** Non-fiberglass casting tape with elastic, knitted polyester substrate, available in a variety of printed patterns.
- **Delta-Cast®** Non-fiberglass reinforcement strips with elastic, knitted polyester substrate, available in white only. Strips are for reinforcing synthetic cast.

Description

Delta-Lite® Casting Tapes, Reinforcement Strips and Splints, as well as Delta-Cast® Casting Tapes consist of knitted substrates impregnated with a polyurethane resin. Curing of the resin is initiated by exposure to ambient humidity or water, causing the tape to become rigid. A cast made from Delta-Lite® and / or Delta-Cast® products sets in approximately 3 to 5 minutes and is loadbearing about 20 minutes after setting. Times vary with cast type and environmental conditions. Finished casts and splints are lightweight, strong, porous and radiolucent.

Intended use and indications

Synthetic cast and splint bandages are intended for external rigid immobilization through casting and/or splinting procedures. The purposes for external rigid immobilization include:

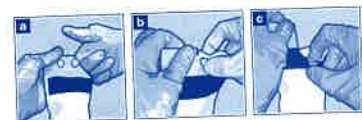
- Immobilization of bone fractures
- Treatment of soft tissue and joint injuries
- Immobilization within treatments for correction or prevention of anatomical deformities
- Specialized orthotic and prosthetic applications
- Total contact casting used for off-loading purposes

The decision on how to apply the products is always made by qualified healthcare professionals.

Directions for Use

The products are intended to be used by qualified healthcare professionals.

1. Place appropriate padding over the entire area to be immobilized.
2. Wear protective examination gloves during application to prevent direct contact with uncured resin.
3. Select the appropriate width of Delta-Lite® or Delta-Cast® casting tape
4. Open each package just prior to use, and open one roll at a time.
5. Opening of package:
 - a Put top of fingers in finger hole to get grip.
 - b Put thumb aside the notch and with the other hand
 - c Pull towards your body and down
6. Immerse the roll into clean, room-temperature water (20-25°C, 68-77°F) and firmly squeeze 1-3 times while it is immersed; remove and slightly squeeze to remove excessive water. The more squeezes the faster set time (3 squeezes typically provide you a set time of approx. 3 minutes). Warmer water also shortens the set time while cold water lengthens it. Warmer water gives a higher exotherm.
7. Delta-Lite® and Delta-Cast® Casting Tapes: Wrap the cast tape in a spiral motion, overlapping each previous layer ½ to 2/3 width of tape. To ensure a snug fit, wrap with slight tension on the tape. Exercise caution to ensure that the tape is not being applied too tightly. Delta-Lite® Reinforcement Strips: Immerse in room temperature water and incorporate in areas requiring extra reinforcement and cover with an additional layer of tape. They can also be used on their own to construct rigid orthopedic splints or braces.
8. Delta-Cast® Cast Tape provides the option in rigidity and can be used to stabilize, provide functional support or completely immobilize the injury. The amount of rigidity is determined by the number of layers used (The more layers used, the more rigid the cast). Apply 2 to 4 layers of casting tape for non-weight bearing areas of immobilization and 5-8 layers in weight bearing areas. Delta-Lite® Cast Tape, on the other hand, is strictly for rigid immobilization. Apply 2 to 4 layers of casting tape for non-weight bearing areas of immobilization and 5-8 layers in weight bearing areas.
9. For good lamination, smooth and rub the tape between layers and overall on the finished cast. Molding of the cast is achieved by maintaining the desired position for about 30 seconds as the material begins to become rigid.
10. Delta-Lite® and Delta-Cast®: Casts and splints set in approximately 3 to 5 minutes. Weight bearing is possible about 20 minutes after setting. Times will vary with cast type and environmental conditions.
11. Window or trim with BSN medical shears or BSN medical oscillating cast saw if desired as soon as the cast has set.
12. Casts may be reinforced or patched with additional tape or splints. Fresh tape should be overlapped upon itself with a possible second gap, application must be wet on wet, to secure it to the original cast.
13. All casting tapes, strips, and splints are radiolucent. Use X-ray machine settings similar to those for areas not covered by cast.



14. Delta-Cast® products can be removed with a scissor. For Delta-Lite® and Delta-Cast applications using more than 5 layers require usage of an oscillating cast saw with sharp blade for removal. A blade that is not sharp can result in heat build-up and possible patient injury. Make sure the cast is completely dry before applying the saw, as a wet cast also leads to heat build-up.

Warnings and Precautions

- Any wound must be dressed prior to application of the splint
- 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
- Instruct patient that cast/splint feels warm during setting
- Excessive exotherm can cause burns. The following are factors that can increase heat:
 - Dipping in water above 25°C (77°F)
 - Too many squeezes in water when activating
 - Expressing too much water from the tape
 - Excessive layering
 - Restricting air flow, for example by:
 - Using elastic bandages
 - Covering the cast with a blanket
- Apply extra padding if required, e.g. on bony prominences
- Instruct the patient:
 - Caution against activities too vigorous for their injury or for the integrity of the cast
 - Immersion in water is allowed only when approval from a qualified medical professional and when waterproof padding (Delta-Dry®) is used. Blot with towel to remove excess moisture.
 - 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
 - Do not insert foreign objects under the cast
- Do not use if the package is already open or damaged Product should be soft and pliant all over
- Do not reuse the device

Uncured polyurethane resin contains isocyanates, which may cause sensitization by inhalation and may cause eye and skin irritation. The resin contains a very low volatility form of isocyanate in its unhardened state. Air sampling, which has been conducted, indicates that isocyanate is not present in detectable amounts during application of synthetic cast tapes.

Storage

Delta-Lite® and Delta-Cast® Casting Tapes and Reinforcement Strips are supplied in individual packages. Puncturing package prior to use will result in premature setting. It is recommended to store the product at room temperature (15-25°C / 59-77°F). Short term exposition to higher temperatures is tolerated. Prior to opening, gently squeeze; product should compress with finger pressure. Do not use hardened product. Expiration date is listed on the label of every package stating year-month. For best results it is recommended that stock be rotated vertically every 3 to 6 months during prolonged storage.

Flammability

Uncured polyurethane tape will burn over open flame. Cured cast will not normally support combustion as defined by the USA Flammable Fabrics Act (CS-191-53) and NFPA Standard (#702-1975).

Disposal

Casts may be incinerated or land filled in accordance with local regulations. Pouches must be opened to allow hardening before disposal of unopened product.

Notice

Any serious incident that has occurred in relation to this device should be reported to BSN medical Inc. (BSN medical GmbH within the European Union) and the competent authority of your state.