3M[™] Primacast[™]

Unpadded Splint

(English)

Description

The 3M Primacast Unpadded Splint consists of multiple layers of a knitted fabric, impregnated with moisture-curable resin. Exposure of splint to moisture or water initiates a chemical reaction which causes the splint to become rigid. A finished splint is lightweight, strong, and radiolucent.

Intended Use

Primacast unpadded splint is intended for use in the construction of common orthopedic splints. Specific splinting application suitability should be the responsibility of a qualified, medical professional.

Precautions

- With any medical device which covers the skin, there is potential for skin maceration. Maceration has been reported with use of this splint. Use clinical judgement for use on patients for whom maceration may be of concern.
- Clean water that feels cool (70-75°F/21-24°C) to the touch should be used for application. Warming the water is not necessary for speeding up the setting time, extra squeezes in the water is all that is needed. Caution should be exercised when using water warmer than 75°F (24°C), as this may increase exotherm (temperature of the splint while curing), and the possibility of discomfort or thermal burns to the patient. If applying splints on a regular basis, change dip water at least once a day.
- Protective gloves must be worn while handling the unpadded splint. The resin will adhere firmly to unprotected skin and to clothing. Care should be exercised to avoid contacting unprotected areas of the patient's skin during application. If resin should come in contact with skin, swabbing lightly with alcohol while uncured, or acetone if resin has cured may help in removing.
- Providing extra splint layers through folding or other means may result in the possibility of discomfort or thermal burns to the patient. The splint can be customized by trimming with scissors.

Instructions for Use

Wound management, fracture reduction, post-surgical care, and general patient supervision should follow established practices.

- 1. Apply stockinet and/or padding to the extremity.
- 2. Protective gloves must be worn while handling the unpadded splint.
- 3. Select the desired size splint and remove from the foil pouch.

- 4. Remove the blue cover from the splint and trim the splint as needed for fit.
- Note: The fabric covering can be used to prevent the elastic bandage from adhering to the splint if so desired. This is done by placing the fabric covering length-wise across the outside of the splint after application before the splint is wrapped with the elastic bandage. Since the fabric covering has resin on it, handle it with care to avoid contact with skin or clothing.
- 5. Immerse the splint in cool temperature (70-75°F) water, remove and squeeze out excess water.
- Note: Giving extra squeezes while the splint is immersed will shorten the setting time without the need to warm the water. During the curing process the splint will exhibit an exothermic reaction (an increase in the temperature of the splint while curing).
- 6. Apply the splint and secure in place by wrapping with an elastic bandage.
- 7. Mold and maintain the correct position of extremity until the splinting material is set (approximately 3-4 minutes).

Storage

Product should be stored at room temperature (59-86°F/15-30°C). Each splint is packaged in a sealed foil pouch. Care should be taken to avoid puncturing the pouch, as this will cause the splint to harden prematurely in the package. Each pouch should be gently squeezed prior to opening to check suitability for application. The splint should be soft and pliant. Do not use a splint that feels hard. Each box is marked with an expiration date. For optimum performance, refer to the date of expiration to aid in rotating stock.

Explanation of Symbols:



• Attention, see instructions for use.

[LOT]

2000-10 AZ

• The lot in a box and the hourglass symbols are symbols that represent lot number and expiration date. The hourglass is followed by a year and month which represent the expiration date (year and month: 2000-10). The entire line after the hourglass represents the lot number (2000-10 AZ).

② • Do not reuse.

