General IFU for Bone Foam Positioners

This manual contains information necessary for the normal use of the product. It is intended to be used in conjunction with the product specific instruction for use. Before you make use of the product, make sure to read and understand in detail the contents of both instructions.

Safety Information

The techniques detailed in this manual are only manufacturer's suggestions. The final responsibility for patient care with respect to this device remains with the attending physician. Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Keep this manual available for future reference.

Manufacturer

Bone Foam, Inc.
20175 County Road 50
Corcoran, MN 55340

www.bonefoam.com

Email: customerservice@bonefoam.com
Phone: (763) 559-1830
Toll-free: 1 (877) 861-2663
Fax: (763) 559-1822

BONEFOAM®
Position for Excellence

General Positioners

Safety Precautions and General Information:

- Keep out of direct sunlight. This may cause discoloration of product.
- Avoid using the product if package is damaged during transportation.
- Prior to using this device, read the Directions for Use.
- To prevent patient and/or user injury and/or equipment damage, examine the device for potential damage or wear prior to use - do not use the device if damage is visible, if parts are missing, or if it does not function as expected.
- Do not submerge the device into water. Equipment damage can occur

Cleaning and Disinfecting Instructions for Bone Foam Products:

- Do not sterilize the device. This device is not intended to be sterilized.
- After use, wipe the product with a clean wipe and disinfectants. The following disinfecting materials are known to be compatible with Bone Foam products:
  a. Rubbing alcohol (70% isopropyl alcohol)
  b. General Purpose/All Purpose Cleaner
    i. Read and follow the cleaning product's instructions.
- Make sure that the device is dry before you store it or use it again.

Safe Disposal Instructions:

Customers should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories.

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MD Medical Device
LATEX Latex Free
NON STERILE Non Sterile

Rev: 0

Symbol Glossary:

Symbol	Description	Reference
	Indicates the device is a medical device	MDR 2017/745
	Indicates the European Authorized Representative name and address in the European Community	MDR 2017/745
	Indicates the medical device manufacturer	EN ISO 15223-1
	Indicates the manufacturer's lot number	EN ISO 15223-1
	Indicates the medical device Global Trade Item Number	21 CFR 830 MDR 2017/745
	Indicates the date when the medical device was manufactured	EN ISO 15223-1
	Indicates the manufacturer's catalogue number	EN ISO 15223-1
	Indicates the unique device identified information for the device	EN ISO 15223-1
	Indicates the device is not sterile.	EN ISO 15223-1
	Indicates the need for the user to consult the instruction for use	EN ISO 15223-1
	Indicates the device does not contain natural rubber or dry natural rubber latex.	EN ISO 15223-1
	Indicates the device is for re-use	EN ISO 15223-1
	Indicates the device is single patient use.	EN ISO 15223-1