PRODUCT

Dermal Biopsy Blade (Sterile) #A750-DBB

(Stainless Steel, Plastic)

Sterilized by Gamma radiation of minimum 25 kGy and not more than 32 kGy (2.5 M Rads to 3.2 M.Rads)

DEVICE DESCRIPTION

Dermal blades are made of stainless-steel blades mounted on flexible PP holder. The device is packed in a soft blister pouch. The device is sterilized by Gamma Radiation and Expiry is 5 years from the date of manufacturing.

INTENDED USE

The device is intended for cutaneous surgery giving smooth clean excisions with less tissue trauma. It is used to remove surface protuberances, flat lesions, or deep lesions by
saucer-shaped incision. Dermal biopsy blades are made of stainless-steel blades mounted on flexible plastic holder. This disposable device is a surgically invasive device and for transient use. It covers
under surface device (nature of body contact) and contact with intact skin & mucosal membrane.

MODE OF ACTION:

Hold plastic teeth with tension applied to both sides to create curvature shape of blade. The sharp surface is brought beneath the lesion or any protuberances for removal.
It should be used soon after opening from the primary pack.

INDICATIONS

– Raised lesion removal
– Lesions that separate easily from deeper skin
– Removal/shave of extra tissue from body surface
– Do not use in cardiac/ ophthalmic surgery

CONTRAINDICATIONS

– Re-used blades can work as a carrier for communicable disease to patient and/or user.
– Adverse events may happen if blades are used after expiry date listed on the product.
– Do not use other than surgical surgery.
– Do not use it if the patient is allergic with metal.
– Do not use it in cardiovascular, ophthalmic surgery or neurovascular surgery.

PATIENT TARGET GROUP

– The device can be used on all patients.

INTENDED USERS

– The device shall be used by licensed medical practitioners or paramedical staff.

PREPARATION FOR DECONTAMINATION

– No requirement.

APPLICATION ON THE BODY

– Intact skin & mucosal membrane.

CLEANING AUTOMATED

– No cleaning is required before use of the device.

CLEANING MANUAL

– No cleaning is required before use of the device.

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Made in India

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DISINFECTION
– No disinfection is required.

MAINTENANCE
– No requirement.

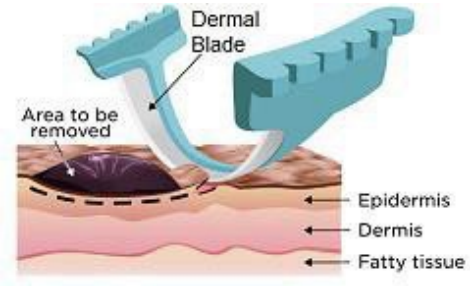
INSPECTION & FUNCTION TESTING
– Inspect the medical device for proper functionality. Visually inspect for damage.

ADDITIONAL INFORMATION
– NA

DESCRIPTION OF COMPONENT PARTS
– None

SYSTEM PREPARATION
-- Check the label for manufacturing and expiry dates (do not use the medical device after expiry). Make sure the package is not damaged. Visually examine the pouch to see if there is any damage.

INSTRUCTIONS FOR USE
– Do not use if package is broken or product shelf life is expired.
–Peel off the device from the soft blister individual packing from the peel-open side.
–To use, hold the plastic teeth, one side with thumb & other side with forefinger with tension applied to both sides to create a curvature shape of the blade shown below.
– Brought the sharp surface beneath the lesion or any protuberances.
– Slightly pressure on the skin with the blade and remove the desired tissue.
– Incision must place as per the desired length preferably measured and marked.
– After use, products must be disposed of in a sharp container.



WARNING
– Read instruction for use
– The product should be used only by a licensed healthcare practitioner.
– Before use always check integrity of product and packing and the expiry date.
– Single use only. If re-used, it can work as carrier for communicable disease, HIV, Hepatitis, contagious diseases, undue diseases to patient and/or user.
– Use product immediately after opening the pack
– AD Surgical is not responsible for any possible consequences resulting from improper use.
– Sterility of product is not guaranteed if packet is broken/torn.
– Do not re-sterile. Do not re-use the device.
– Keep out of reach of children.
– Used devices must be disposed of in a sharp container and processed by a regulated medical Removal service according to state

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and local regulations.

PRECAUTIONS:

– Always open the pouch from peel apart direction to avoid injury.
– Devices are extremely sharp, use care while handling.
Devices should be used in a sterile environment. Proper procedures must be used as applicable for handling any sterile product.
– Carefully dispose the device to avoid any contact or injury due to the sharp nature of the device.
– Proper care must be taken while using the device to avoid any injury or accident.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

– Difficult to cut at incision site during reuse.
– It may cause contamination.

STORAGE CONDITION:

– Keep away from direct sunlight.
– Keep away from humid environment.
– Storage temperature should be 10 to 40^{o}C
– Humidity of storage area should be 35% RH to 65 % RH.
– Keep away from children.
– Store in dry place.

DISPOSAL SYSTEM

Discard the Device in proper sharp waste container & dispose of the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste

PACKAGING

The device is supplied in a box of 50. The box contains soft blister pouches with external identification on the box.

RETURN OF DEVICE

The return of defective device should be carried out within 90 days from invoice date along with the evidence or damaged product and the product should be unused.

ADVERSE EVENT

The improper use/ misuse of device may cause adverse events to patient or user. e.g., deep cut, injury to user during fitment of blade. Any serious incident that has occurred in relation to the device should be reported to the distributor or manufacturer and the competent authority of the Member State in which the user and/or patient is established.

ELECTRONIC VERSION OF IFU:

Available on the website www.AD-Surgical.com

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