



PRODUCT

SHARD Premium+ Surgical Microsurgical Chisel Blade (Sterile), GMDN Code: 37445

(Sizes: 90, 91)

(Carbon Steel and Stainless Steel), Sterilized by Gamma radiation of minimum 25 kGy

DEVICE DESCRIPTION

SHARD Microsurgical Chisel Blade is made of Stainless steel (Grade F) and Carbon steel (As per BS 2982). The Blade is packed in peel apart Aluminum Pouch with VCI liner to protect the blade from corrosion. The device is sterilized by Gamma Radiation & Expiry is 5 years from the date of manufacturing.

INTENDED USE

The device is used for incision/ cuts during surgery for all blade sizes. The device is under the category of surgically invasive device and for transient use. The device is in contact with intact skin and mucosal membrane.

MODE OF ACTION

Chisel blades are made of Stainless-steel / Carbon steel strip. Consistently sharp, angled cut blade facilitates a clean cut. It can be directly used after mounting on steel collet type handle according to the blade size.

INDICATIONS

- ❖ Dissection Incision.
- ❖ Different size for different thickness of tissue & sight.
- ❖ Removal of extra tissue from operating area.

CONTRAINDICATIONS/ RESIDUAL RISK

- ❖ Re-use of blades can work as carrier for communicable disease to patient and/or user.
- ❖ Adverse event may be happened if blades are used after expiry date as expiry date of product is expiry date of sterility.
- ❖ The Selection and size other than required may affect the intended application of device.
- ❖ Do not use other than surgical surgery.
- ❖ **Do not use if patient is allergic with metal.**
- ❖ **Do not use in cardiovascular and neurovascular surgeries.**

PATIENT TARGET GROUP

The device can be used on all groups of patients.

INTENDED USERS

The device shall be used by qualified surgeons, doctors, 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.



DISINFECTION:

No disinfection required.

MAINTENANCE:

No requirement

INSPECTION & FUNCTION TESTING:

Check for smooth functioning of medical device. 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

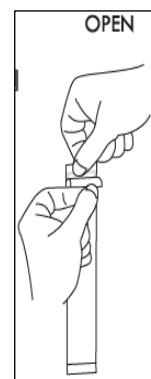
- ❖ Select proper type and size of Blade as per the requirement.
- ❖ Inspect package of Blade for its intactness & expiration date.

Attaching the chisel Blade

- ❖ Peel opens the pouch. Grip the blade with forceps or needle clamp and remove from pouch.
- ❖ Take special care not to grip across the cutting edge of the blade itself.
- ❖ Take the handle loose the collect, now holding on to the thickest part of blade with forceps or needle clamp, insert the blade into collet. Slide the blade back onto the handle and tighten the collet of handle.
- ❖ Choose the sight for incision.

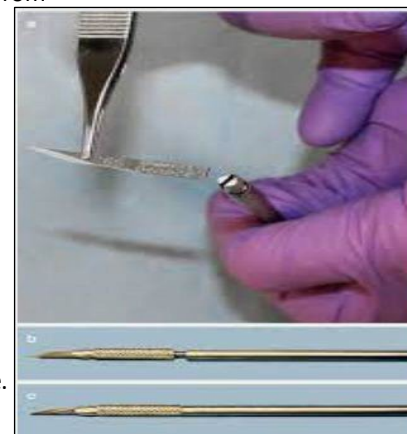
Removing the Blade

- ❖ After using the blade, Loose the collect, now grip blade with forceps/needle clamp and pull up blade from handle.
- ❖ During the surgical procedure, use a containment method of choice, to protect Surgical team from any sharp's injuries, such as a plastic kidney dish.



WARNING

- ❖ Read instructions for use.
- ❖ The product should be used only by a qualified surgeon, Doctor or paramedical staff.
- ❖ Before use always check integrity of product and packing along with expiry date.
- ❖ For single use only, if re-used this 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.
- ❖ Do not use excessive force or use inappropriate equipment.
- ❖ Factory and Distributor are not responsible for any consequences resulting from improper use.
- ❖ Factory and Distributor do not hold any responsibility if device re-used or re-sterile.
- ❖ Sterility of product is not guaranteed if packet is broken/torn.
- ❖ Re-sterilization and re-use of blade cause to change in mechanical properties and material used.



Caution/ Warning
(Read IFU before use)
Keep away
from sunlight



Product Reference/
Art. No.
Keep Dry



Lot Number/
Batch Number
Moisture Limitations



Date of Manufacturing
10°C - 40°C
Temperature Limitations



Use By/Expiry Date
Non Pyrogenic



Manufactured By
Don't Resterilized



European Authorized
Representative
STERILE
Single Sterile Barrier System
Sterilized by Gamma Radiation



Do not use if
package is damaged
MD
Medical Device



Do Not Reuse
IND
Country Code



Consult Mth IFU
CE
2460



- ❖ Re-sterilization and re-use of blade may not meet the intended use as blade may be blunt.
- ❖ Keep out of reach of children.
- ❖ After use of products must be disposed of as per country law of bio-waste handling rule.

PRECAUTIONS:

- ❖ Always open the pouch from peel apart direction to avoid injury.
- ❖ Devices are extremely sharp, Take care while handling.
- ❖ Care must be taken so that the pouch is not opened in an unsterile area, otherwise, the Blade which has already been sterilized by Gamma radiation will become unsterile. Proper procedures must be used as applicable for handling any sterile product.
- ❖ Care must be taken during disposal of the device to avoid any contact or injury due to the sharp nature of the device.
- ❖ Proper care must be taken while getting Blade from the tray to avoid any injury or Accident.
- ❖ In case of changes in the performance of the device for intended use, replace the device with new to full fill the required application.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

- ❖ Difficult to cut at incision site during reuse.
- ❖ Any infectious disease can transfer.

STORAGE CONDITION:

- ❖ Keep away from direct sunlight.
- ❖ Keep away from rain.
- ❖ Storage temperature should be 50°F to 104°F / 10°C to 40°C.
- ❖ The humidity of storage area should be 35% RH to 65 % RH.
- ❖ Keep away from children.
- ❖ Store in a cool and dry place.

DISPOSAL SYSTEM

Discard the blade in proper 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 boxes of 25. The box contained heat-sealed Aluminum peel pouches with external identification on the box.

RETURN OF DEVICE

The return of defective devices should be done as soon as possible. Damaged products should not be used under any circumstances, at any condition.

ADVERSE EVENT:

The improper use / misuse of device may cause adverse event 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 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.

