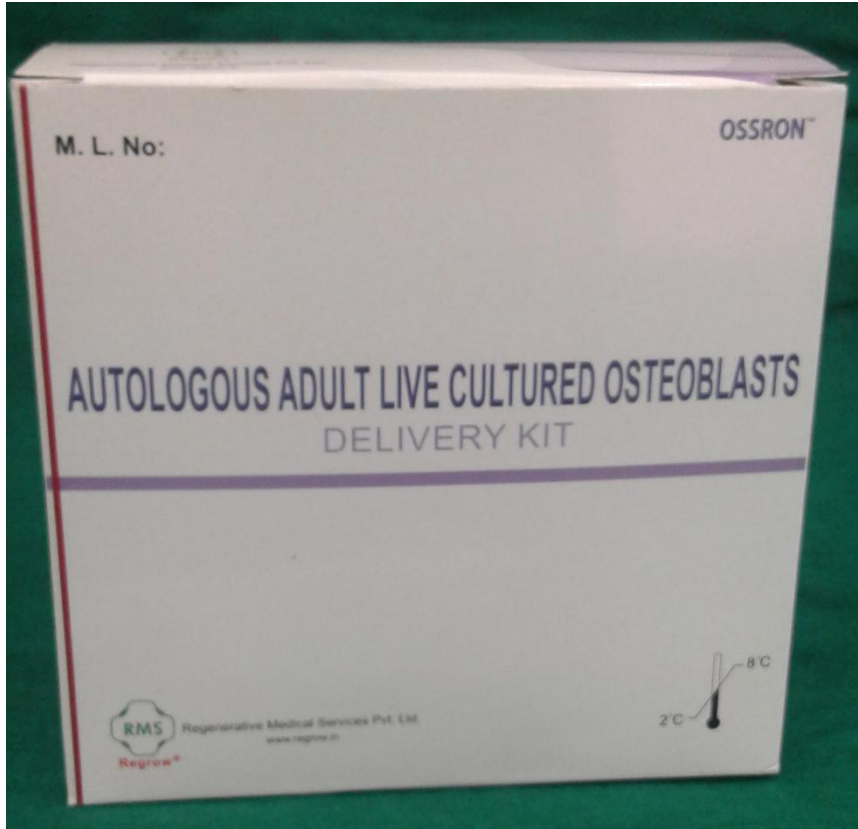


IMPLANTATION MANUAL FOR OSSGROW®

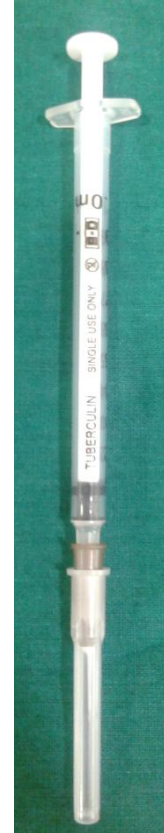
AUTOLOGOUS ADULT LIVE CULTURED OSTEOBLASTS

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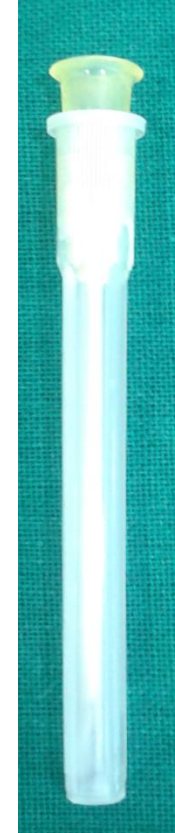
CONTENTS OF PRODUCT BOX



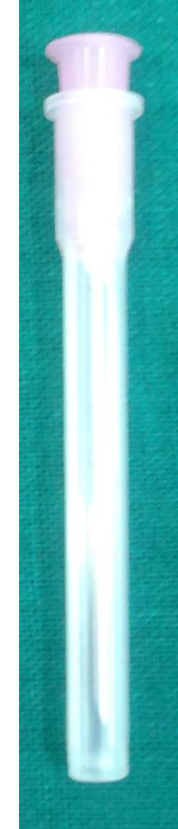
Delivery Kit



**1 ml Syringe
(10 Nos.)**



**20 gauge needle
(10 Nos.)**



**18 gauge needle
(05 Nos.)**

OTHER ASSISTING MATERIAL



Curette

Long Curette No. 3
(10 mm X 3 mm)
L XW= 25.5 X 2cm

Medium Curette No. 2
(9 mm X 3 mm)
L XW= 25.5 X 2cm

Small Curette No. 1
(8 mm X 3 mm)
L XW= 25.5 X 2cm

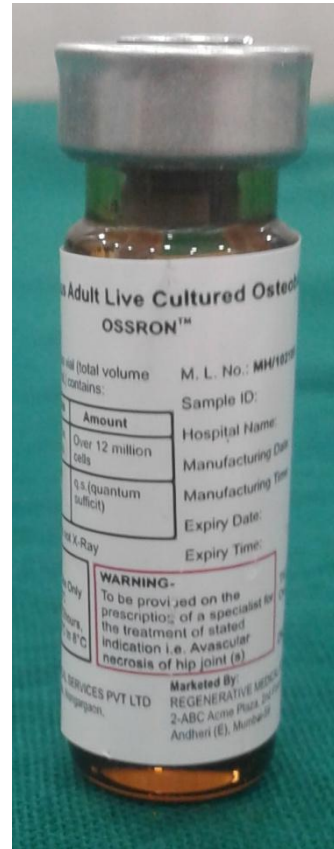


Fibrinotherm

CONTENTS OF DELIVERY KIT



**Outer Vial (Non-sterile)
(Metal Canister)**



**Inner Glass Vial containing final product
(sterile) [Max. up to 04 vials]**

**Final Product: Over 12 million
Autologous Adult Live Cultured
Osteoblasts (OSSGROW®) in 0.4
ml DMEM solution**

INNER VIAL (PRIMARY PACKAGING) LABEL

Autologous Adult Live Cultured Osteoblasts OSSRON™

Composition:

Each single use glass vial (Total volume of Suspension: 0.4 ml) contains:

Autologous Adult Live Cultured Osteoblasts..... Over 12 million cells
DMEM (Dulbecco's Modified Eagles Medium) ...|..... q.s.

INDICATION: Treatment for Avascular Necrosis of the hip joint.

CAUTION:

- For Autologous Use Only
- The product shall be transported and monitored at 2°C to 8°C
- Shelf Life up to 72 hours, when stored at 2°C to 8°C
- Do not use if there is visible change of color of solution from Red to Yellow or Brown
- Do not mix with other solvents or components

Sample ID:

Hospital Name:

Manufacturing Date:

Manufacturing Time:

Expiry Date:

Expiry Time:

WARNING

- Do not Freeze
- Do not expose to X-Ray

M. L. No.: MH/102269

Manufactured By:

REGENERATIVE MEDICAL SERVICES PVT LTD

S. No. 43, Plot No. 22, Shah Industrial Estate,
Nangargaon, Lonavla, Pune -410401

Marketed By:

REGENERATIVE MEDICAL SERVICES PVT LTD

2-ABC, Acme Plaza, 2nd Floor, Andheri –Kurla
Road, Andheri (E), Mumbai-400059

TM: Trademark owner of Ossron

DK/OS/V/01

OUTER VIAL (SECONDARY PACKAGING) LABEL

Autologous Adult Live Cultured Osteoblasts OSSRON™

Composition:

Each single use glass vial (Total volume of Suspension: 0.4 ml) contains:

Autologous Adult Live Cultured Osteoblasts..... Over 12 million cells
DMEM (Dulbecco's Modified Eagles Medium) q.s.

INDICATION: Treatment for Avascular Necrosis of the hip joint.

CAUTION:

- For Autologous Use Only
- The product shall be transported and monitored at 2°C to 8°C
- Shelf Life up to 72 hours, when stored at 2°C to 8°C
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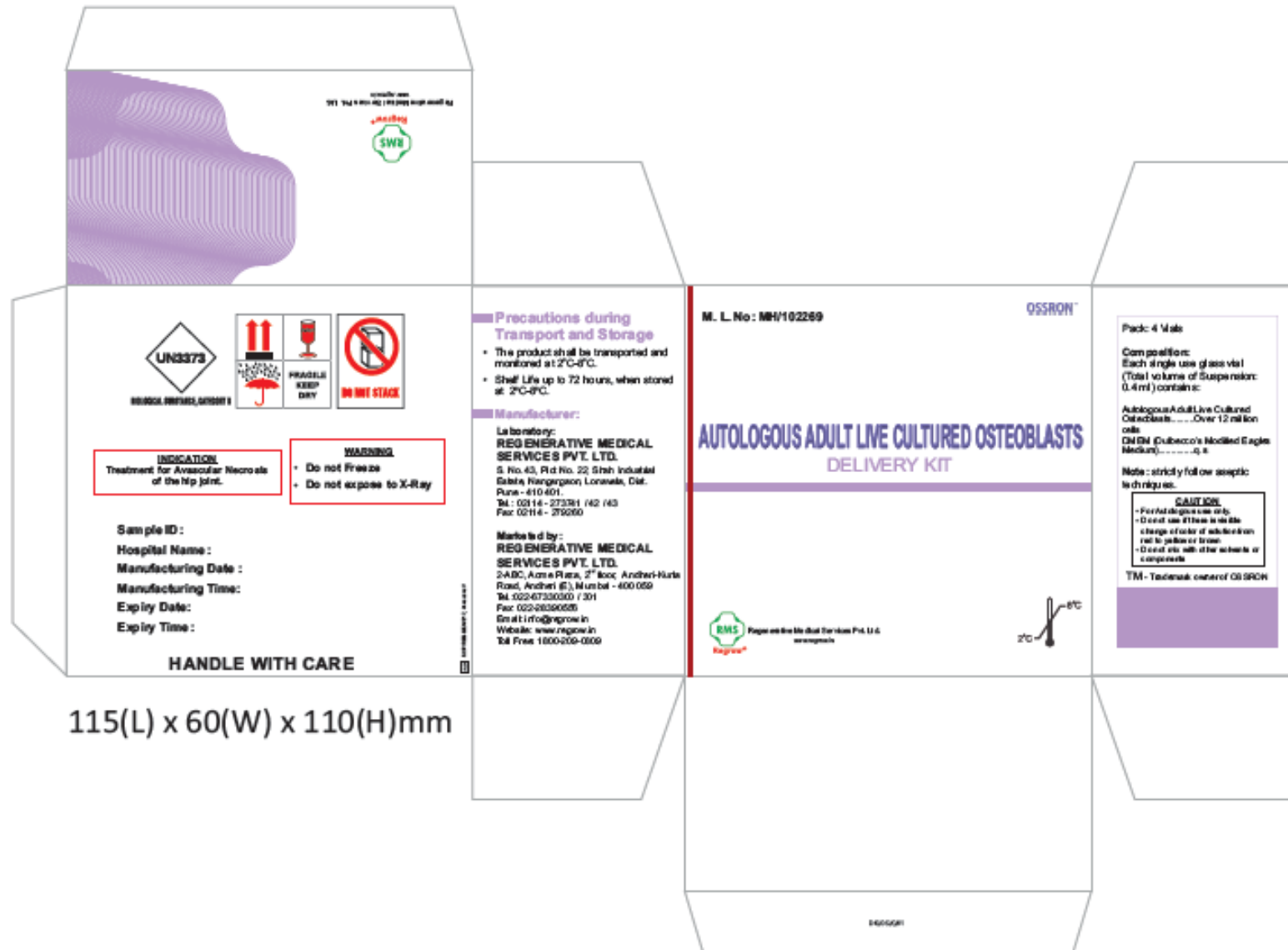
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Road, Andheri (E), Mumbai-400059

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DK/OS/CN/01

CARTON LABEL



PRECAUTIONS BEFORE IMPLANTATION



- Just before implantation, place the Delivery Kit on non-sterile trolley. Remove the Outer Vial(s) from the carton and place it on the same trolley.
- Take out the Inner Glass Vial(s) and with the help of sterile gauze piece wipe the Inner Glass Vial(s) containing final product on sterile trolley.
- If media of inner vial is cloudy or showing any foreign particles, do not use the vial, instead use new vial.
- Do not use the vial if there is visible change of color of solution from red to yellow or brown.
- If any vials in the Delivery Kit are damaged or has caused leakage or mislabeling on vial(s), do not use the vial, instead use new vial.

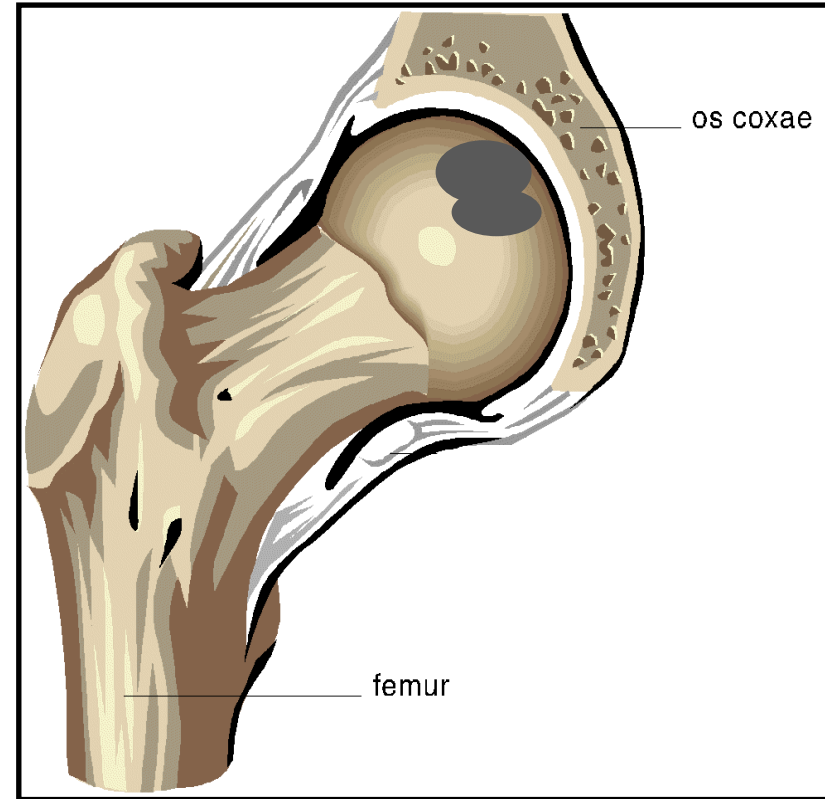
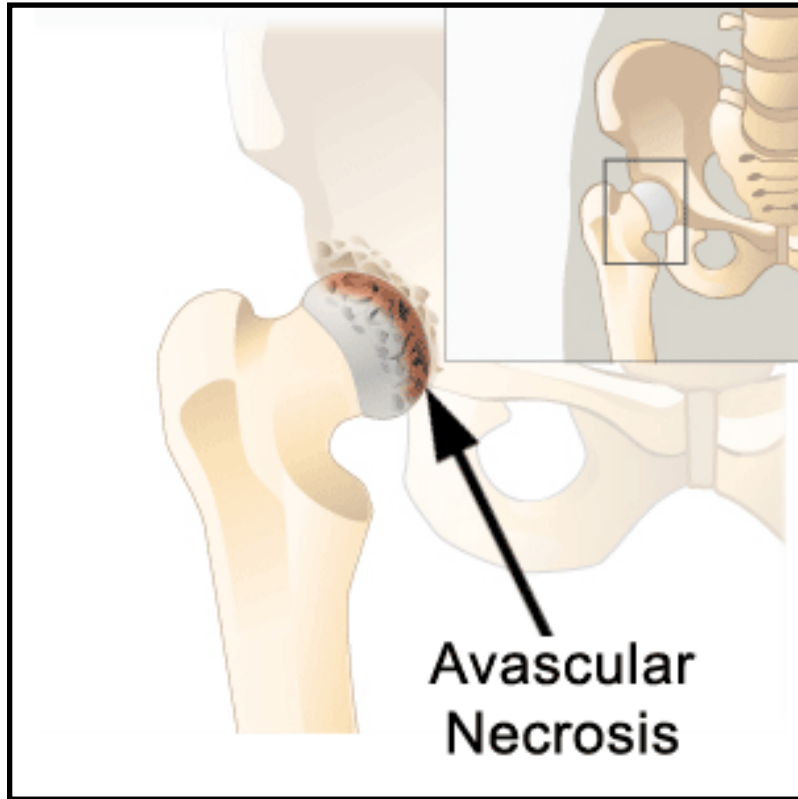
Step 1- Once patient is in optimal position, incision is made to approach the defect size.



An incision taken on lateral side of hip.



Step 2- Treating Physician or Specialist to identify the defect area and defect site.



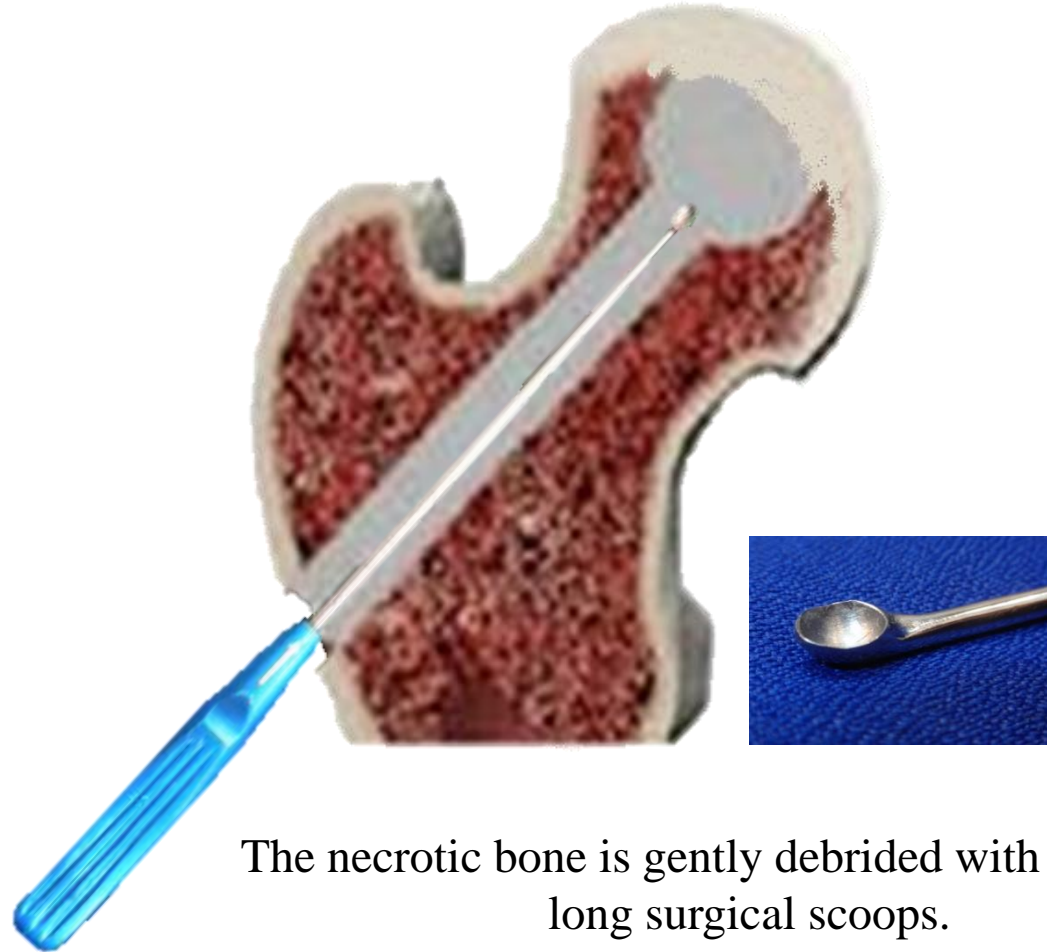
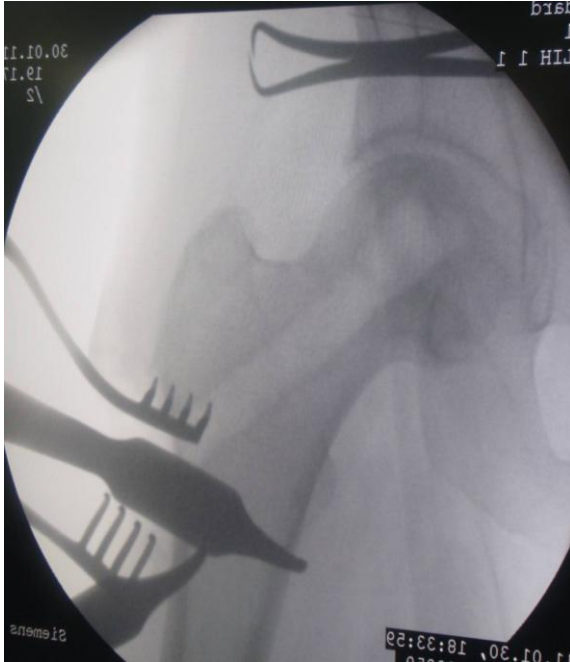
Osteonecrosis of hip joint

Step 3- Core Decompression under C-Arm guidance



Using a 7/9 mm sized reamer, single or multiple drill holes are made by standard core decompression method to approach the necrotic area in the femoral head under C-Arm guidance.

Step 4- Necrotic bone debridement



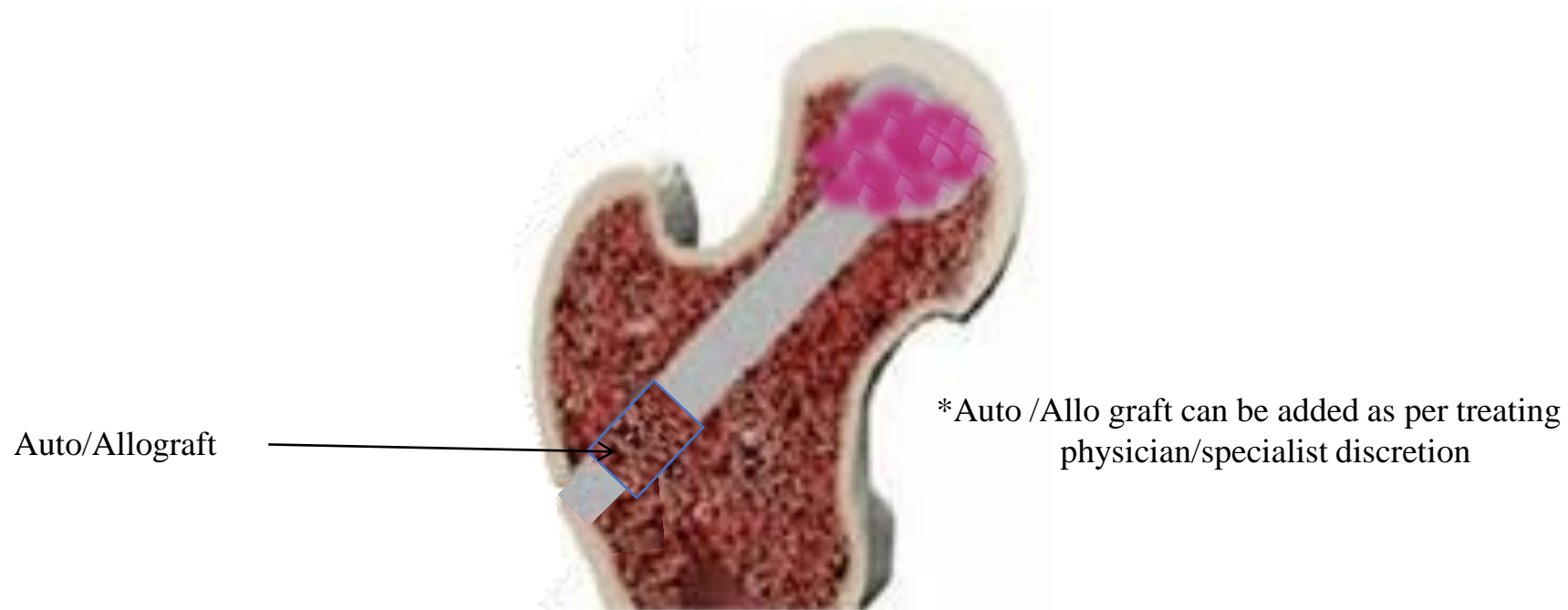
The necrotic bone is gently debrided with the help of long surgical scoops.

Step 5- OSSGROW® Implant



Tilt the table and bring the hip joint of patient into gravity dependent position. Inject **OSSGROW®** using long spinal needles into defect area slowly. During implant, avoid spillage of **OSSGROW®**

Step 5- CLOSE THE SITE OF INCISION



- Wait for 8-10 min after implant and treating physician/specialist may close site of incision with Allograft OR Autograft (taken from pelvic region and prepared using bone masher)
- Perform routine closure of the joint with standard medical procedure of suturing and follow rehabilitation protocol advised by treating physician or specialist.

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