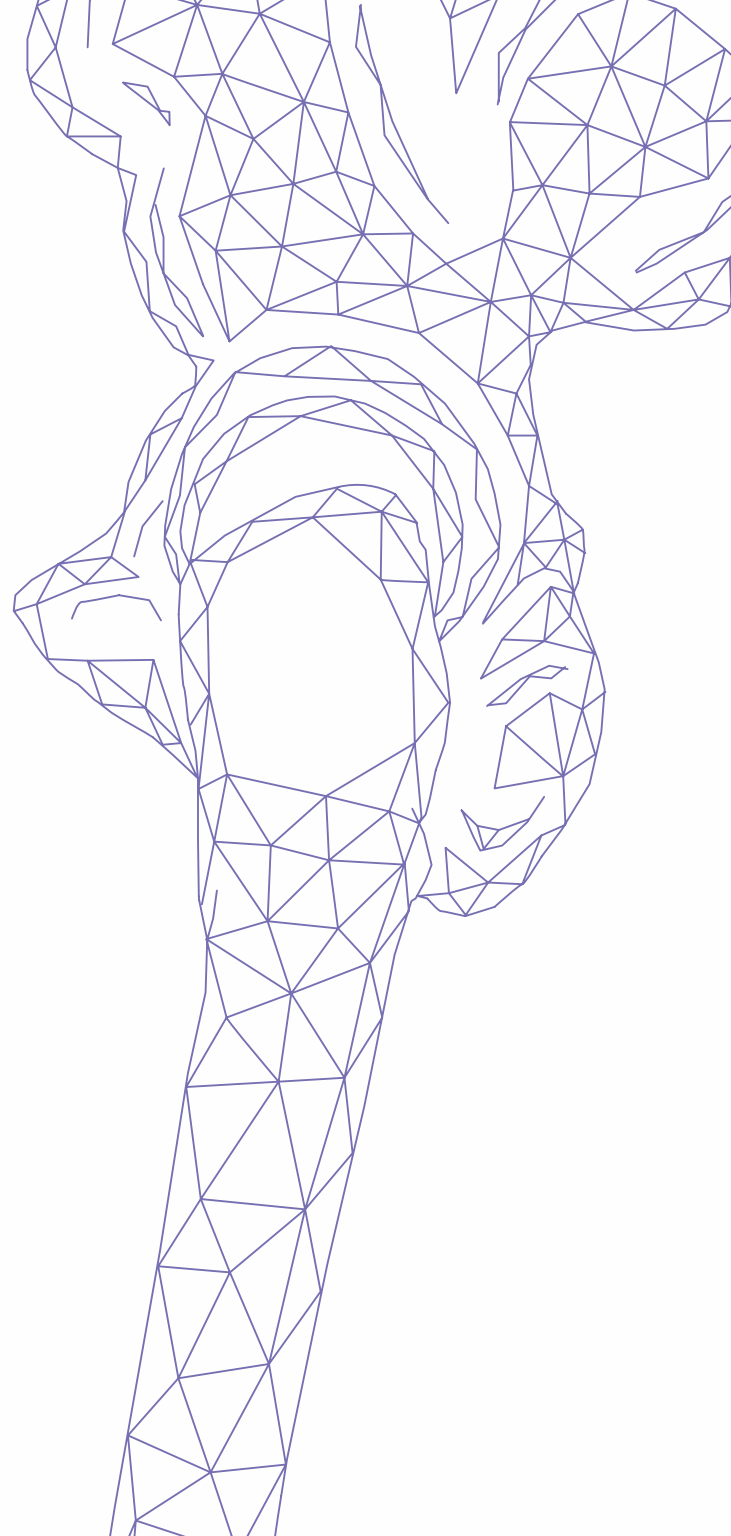




OSSGROW[®]

IMPLANTATION

MANUAL





CONTENTS

	Pg. No.
▶ CONTENTS OF PRODUCT BOX1
▶ OTHER ASSISTING MATERIAL2
▶ CONTENTS OF DELIVERY KIT5
▶ PRECAUTIONS BEFORE IMPLANTATION6

Confidential and Proprietary

© Copyright 2022. Regrow Biosciences Pvt Ltd. All Rights Reserved.



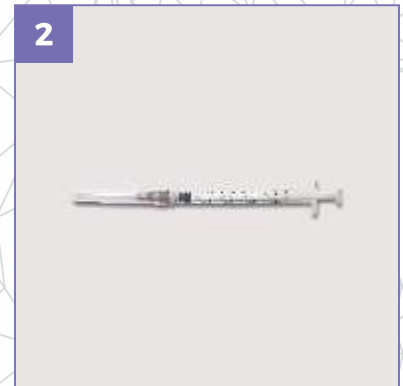
CONTENTS OF THE PRODUCT BOX

1 - DELIVERY KIT

2 - 1ML SYRINGE (10 NOS)

3 - 20 GAUGE NEEDLE (10 NOS)

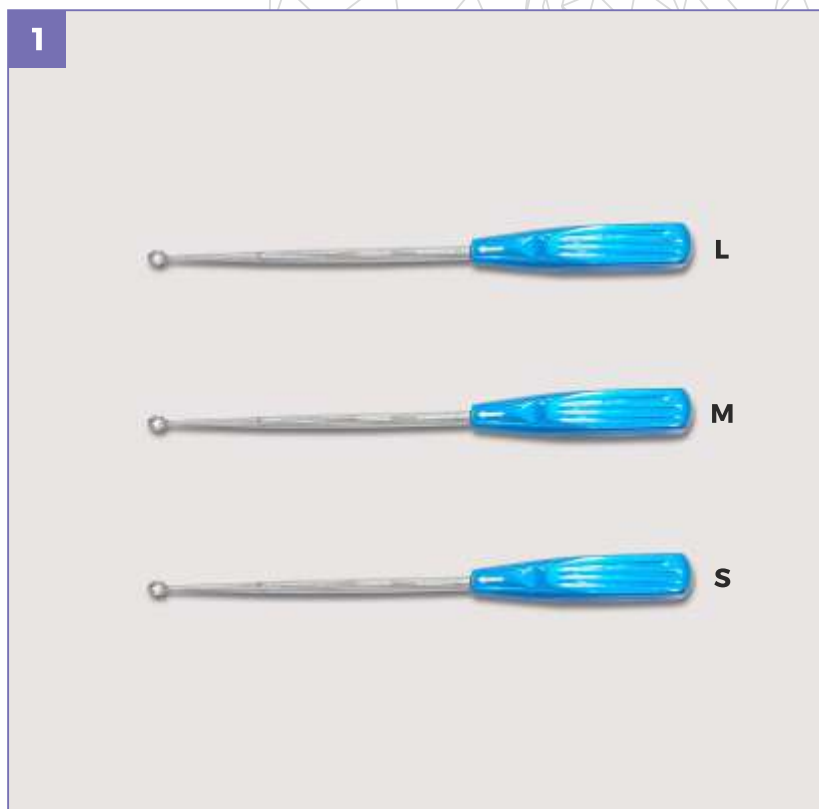
4 - 18 GAUGE NEEDLE (5 NOS)



OTHER ASSISTING MATERIAL

1 - CURETTE

- ▶ **Long Curette No. 3**
(10mm X 3mm) L XW= 25.5 X 2cm
- ▶ **Medium Curette No. 2**
(9mm X 3mm) L XW= 25.5 X 2cm
- ▶ **Small Curette No. 1**
(8mm X 3mm) L XW= 25.5 X 2cm



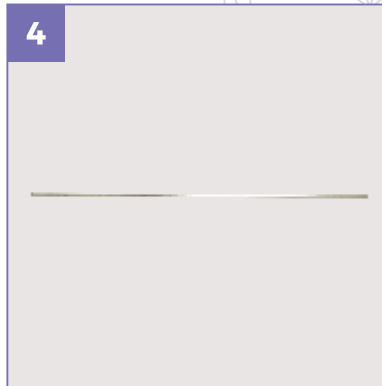
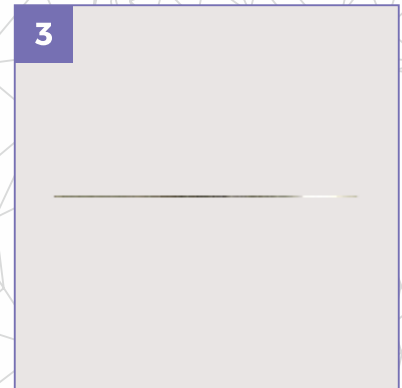
OTHER ASSISTING MATERIAL

2 - FIBRINOTHERM

3 - 2.5MM GUIDE WIRE

4 - 1.8MM GUIDE WIRE

5 - CANNULATED SCREW
DRIVER



OTHER ASSISTING MATERIAL

6 - CANNULATED ACL SCREW

7 - REAMER (8MM)



CONTENTS OF THE DELIVERY KIT

- 1 - DELIVERY KIT
- 2 - OUTER VIAL (METAL CANISTER) (NON-STERILE)
- 3 - INNER CLASS 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



PRECAUTIONS BEFORE IMPLANTATION

Step wise instructions to be followed:

STEP 1

Just before implantation, place the Delivery Kit on non sterile trolley. Remove the Outer Vial(s) and place it on the same trolley.

STEP 2

Take out the outer surface of 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.

STEP 3

If media of inner vial is cloudy or showing any foreign particles, do not use the vial, instead use new vial.

STEP 4

Do not use the vial if there is visible change of color of solution from red to yellow or brown.

STEP 5

If the product is insufficient or not upto the quality standards enlisted on the COA, please initiate recall of the Delivery Kit.

STEP 1

**PATIENT IN SUPINE POSITION
PREFERABLY ON FRACTURE
TABLE**



STEP 2

**APPROACH AND IDENTIFY
NECROTIC AREA**



STEP 3

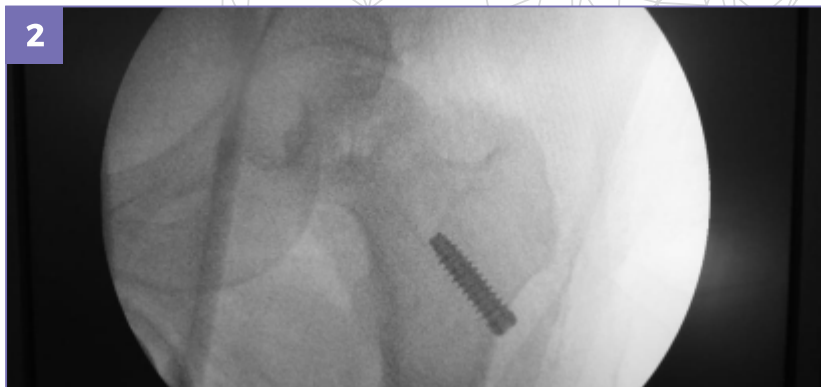
CORE DECOMPRESSION INCLUDING CURETTAGE

- ▶ Decompression using drill bit (**Fig. 1**)
- ▶ Curettage of dead bone tissue using specialized instruments (**Fig. 2**)
- ▶ Open tunnel ready to receive **OSSGROW®** (**Fig. 3**).



STEP 4

INSERTION AND FIXATION OF
CANNULATED INTERFERENCE
SCREW.



STEP 5

INSERTION OF 18G PUNCTURE /SPINAL NEEDLE THROUGH THE SCREW.



STEP 6

ATTACH **OSSGROW®** DELIVERY DEVICE TO NEEDLE AND INJECT FINAL PRODUCT.

STEP 7

REMOVE NEEDLE AND SCREW TO PLUG OPENING WITH BONE GRAFT/WAX OR ANY OTHER SUITABLE MATERIAL.

CLOSE WITH STANDARD TECHNIQUE INCLUDING SUTURES.





FOR MORE DETAILS, PLEASE REACH OUT TO US:

Dr. Charul Bhanji

Technical Director

 +91 9821186618

 drcharul@regrow.in

OSSGROW[®]



REGROW BIOSCIENCES PVT. LTD.

HEAD QUARTERS

2-ABC, Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai – 400059. India

Tel: +91-22-67330300

Toll-Free No.: 1800 209 0309

GMP FACILITY

22, Shah Industrial Estate, Nangargaon,
Lonavala - 410401, Maharashtra, India

Tel: +91-2114-273741/42/43

Licensed By: State Food and Drugs Administration, Pune & Drugs Controller General of India (DCGI), Govt. of India

Disclaimer: "This document contains confidential and proprietary information of Regrow Biosciences Pvt. Ltd. which is intended for personal use of treating physicians or specialists and it intends to serve as a guideline ONLY and not an absolute recommendation for implantation of osteoblast cells. This information can only be used for educational and training purposes and in no way, it intends to define or suggest surgical protocol. The treating physician or specialist determines appropriate protocol and techniques required for implantation of osteoblast cells. The treating physician or specialist should be familiar with the contraindications of performing the implantation of osteoblast cells. Treating physician's or specialist's judgement is required to consider patient's risk factor prior to performing the implantation of osteoblast cells. Regrow Biosciences Pvt. Ltd., its officers, directors, agents, attorneys, employees, shareholders, consultants and affiliates do not take any responsibility or liability if the manual is used by anyone for any other purpose. Regrow and logos containing Regrow brand mark are trademarks of Regrow Biosciences Pvt. Ltd. Other brands are trademarks of Regrow Biosciences Pvt. Ltd. or their respective owners."