



Vitalys Surgical proposes a range of **100% made in France sterile** cranial perforators.

All our cranial perforators have **an auto-release mechanism** and are **single-use**. They have been researched and tested by engineers from a surgical-sector ISO 13485 – approved specialist design consultancy and are appropriate for all cranial anatomies. A patent has been filed to protect the **engage/disengage** concept of the VitalDrill cranial perforator.

This range of innovative cranial perforators is designed to optimise the practitioner's procedures, comfort and safety

- The **anti-skid centring tip** at the start of perforation
- The **optimised milling** of the perforator's cutting teeth
- **Immediate release** at the right moment at the end of each perforation
- **The formation of a bony capsule** at the end of perforation, creating a protective shield between the perforator drill and the dura mater

ADVANTAGES :

- Ready to use, sterile (gamma rays)
- Impossible to remove, do not re-sterilize
- No bad cut of the drill
- No handling while sterilization
- No packaging
- Excluding the responsibility for the hospital
- Savings for the hospital on all aspects (safety, handling and sterilization)
- No sterilisation (autoclave)

PRECAUTIONS FOR USE

- ✓ Using aseptic technique open the blister pack and pass into sterile field.
- ✓ Connects the Vitalys perforator blade to the perforator handpiece with the Hudson connector. Ensure the Hudson connector is secure.
- ✓ The neurosurgeon should apply a light pressure on the handpiece throughout the drilling and not release the pressure until the automatic clutch has disengaged. (do not stop the drilling once commenced)
- ✓ **NB:** *do not apply as much pressure on the handpiece as is required when using the competitors perforators. The perfect cut Vitalys perforator blade is designed to be used with less pressure applied than the competition.*
- ✓ Ensure a perpendicular (90°) angle of drill & handpiece is maintained in any cranial position (parietal, frontal, occipital and temporal) at the start and throughout the perforator drilling. Irrigation during the drilling is required.
- ✓ Up to four burr holes can be made with the same Vitalys perforator blade.
- ✓ A craniotome blade can then be used to complete the cranial flap.
- ✓ After the flap is open the bony capsules can be easily unplugged from the perforator.



www.vitalys-surgical.com

VITALDRILL

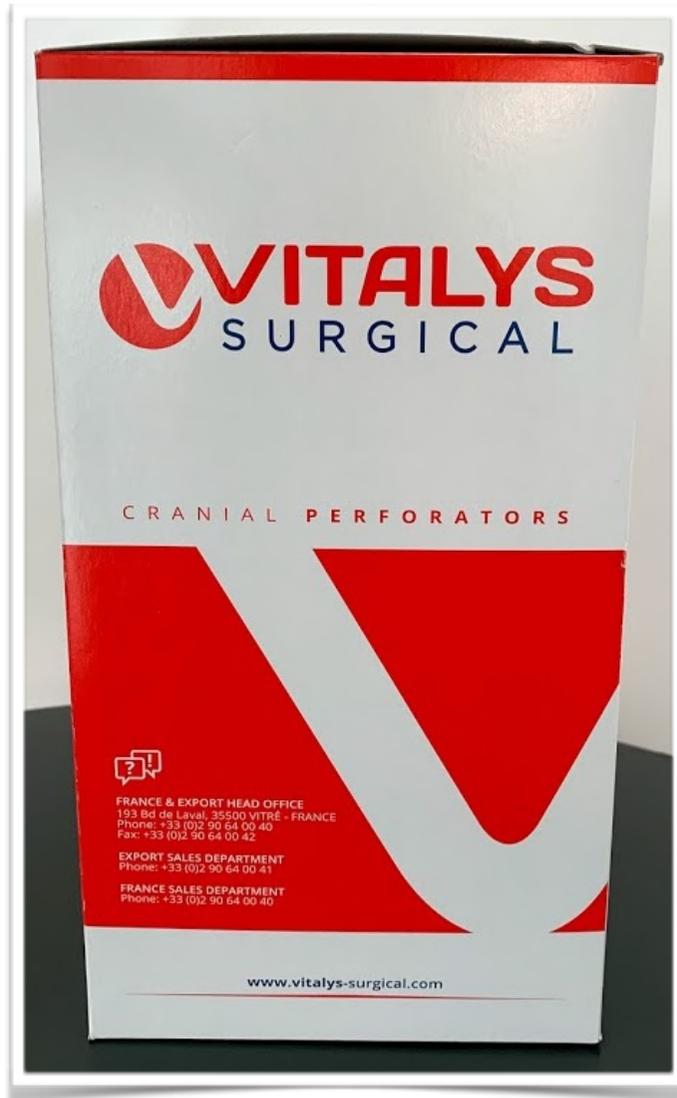
SINGLE USE CRANIAL PERFORATOR

- ✓ **ADULT** (Product Ref. 0106-03-00)
- ✓ **TEENAGER** (Product Ref. 0106-02-00)
- ✓ **PEDIATRIC** (Product Ref. 0106-01-00)



PACKAGING :

- Carton Box of **20 units**
- 20 units Individual Cardboard Box in plastic film inside
- **Coloured sticker** fixed on the side of the individual cardboard box (*Adult : Black ; Teenager : Blue ; Pediatric : Yellow*)
- IFU in **11 languages** and 2 Patient Traceability labels inside the unit cardboard box.



The Cranial Perforator is packaged in a sterile Blister Pack.



Important Points

Cranial Perforator for **single use only**, do not resterilize ;
The cranial perforator is **not removable** thus creating the risk of **deterioration** of the product and may make it **unusable** ;

Do not soak the product in a decontamination solution as this may damage the **clutch engaged/disengaged system** and on the other hand a risk to infect the new patient (HIV...) or other virus ;

Do not use the autoclave process (example 134 °C during 18 min) as this may deform the color crankcase and may make it unusable ;

If the cranial perforator is resterilized and is deficient during the intervention, you do this entirely at your own risk and the responsibility of the hospital as well.

Highspeed Surgical Motor System Programmation Setting

The main highspeed Surgical Motor System with rpm rotation speed developed for Neurosurgery indications is *Aesculap, Bien Air, Stryker, Nouvag, NSK or Midas Rex (Medtronic)*. Our cranial perforators are supplied with a Hudson coupling tip designed to be fitted to a surgical motor having a handpiece equipped with a Hudson coupling mandrel. These motors all have in common a programmable console from 10,000 to 80,000 rpm depending on the type of intervention.



We highly recommend to use the console with **900/950 rpm** rotation speed corresponding to **60,000 rpm** for **Adult** Perforator. Indeed, the Hudson coupling mandrel where the perforator is connected, is a reduction system (gear ratio).

For example, if the programming of the rotation speed is 60,000 rpm, this corresponds to a rotation speed of 950 rpm with the gear ratio output of the Hudson mandrel connection.

In fact, the gear ratio divides per 60-65 the start of the rotation and/or speed at the output of the console to give a speed much less slower to the Hudson mandrel.

However **800 rpm** should absolutely be required for the **Teenager** and **Pediatric** perforators which correspond to **50,000 to 55,000 rpm**.